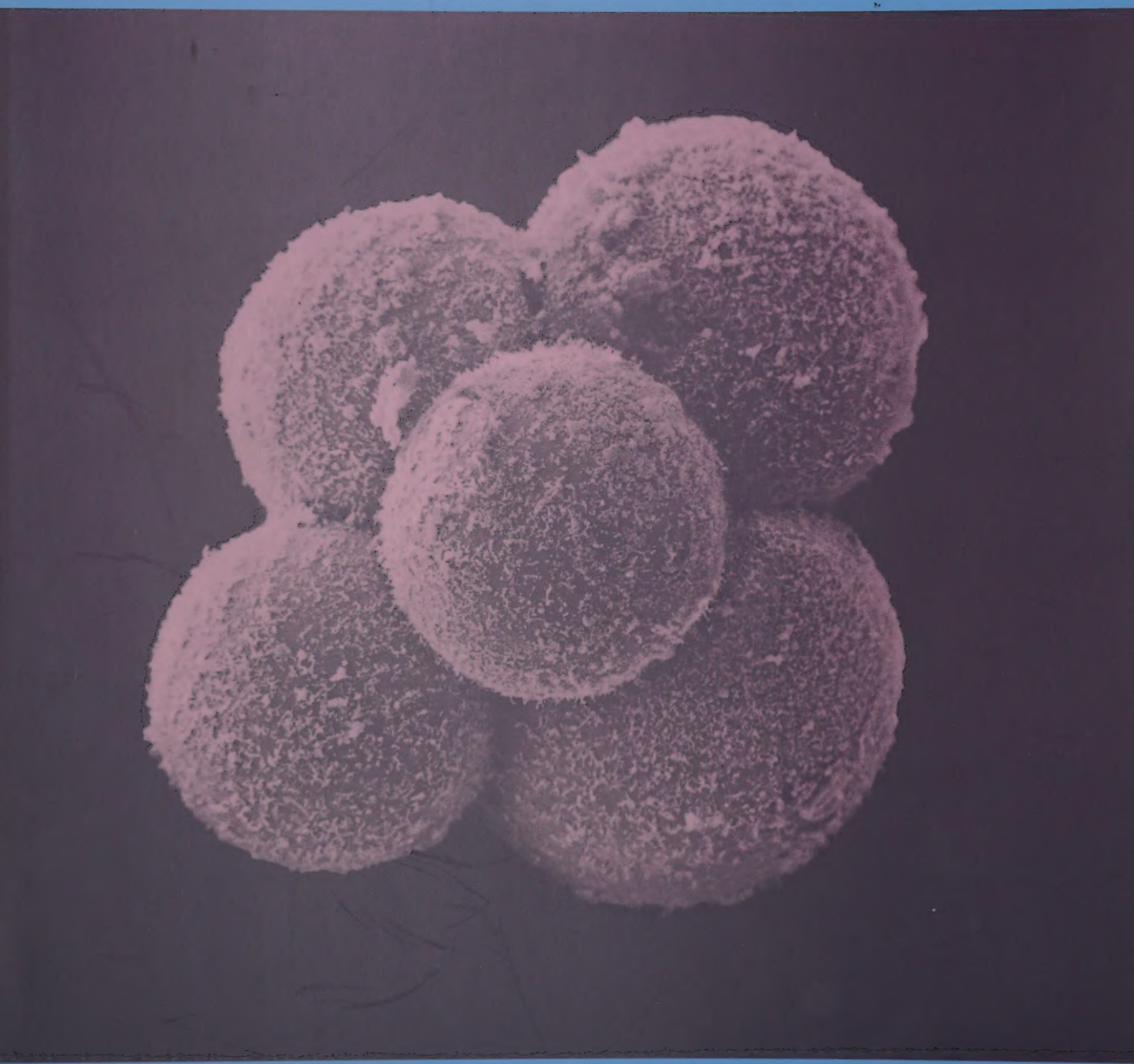


Human Fertilisation and Embryology Authority **Twelfth Annual Report and Accounts 2002/03**

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

This report covers the year to 31 August 2003 with a forward look for the year to August 2004.

Contents

Chair's Introduction

This annual report comes in a very special year for assisted reproductive technology – the 25th anniversary of *in vitro* fertilisation (IVF). It has been a time for celebrating the families created by assisted reproductive technology, as well as those professionals who work to ensure the safe creation of the 8,000 babies who are born each year in the UK following IVF.

The developments in assisted reproductive technology over the last quarter of a century since that first IVF birth have been remarkable. The HFEA regulates across public and private sector treatments alike and has played an important part in the success of IVF and donor insemination. Strong regulation is absolutely vital to continued public and patient confidence.

The HFEA also has responsibility for regulating embryo research in the UK, an area that is of considerable interest to the public. We are pleased to see the results of a recent opinion poll which showed that 70% of the public support stem cell research for medical benefits. We consider that this level of support is due in no small part to the public confidence that regulation of this area has engendered. The HFEA will continue to ensure that Parliament's wishes in this growing area are strictly abided by.

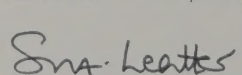
For our part, 2002/03 has been a year of considerable activity. The HFEA has become a more robust, transparent and collaborative organisation. We have strengthened our regulation and inspection processes, we are improving our IT functions and we have launched a new website which allows patients much improved access to relevant information. We are incorporating patients' experiences into our inspection regime and have formally consulted on sex selection and the sixth edition of the HFEA Code of Practice. The results of both consultations will be issued by the end of 2003.

We have also set up formal connections with the General Medical Council so that information from patients can inform their actions.

In opening up our practices to the public, we will be publishing, in late 2003, our Licence Committee decisions and outputs. We will also be holding open Authority meetings and hosting our first embryo research conference. In June 2003, we launched a truly ground breaking alert system; no such system operates either in Europe or the USA. The alert provides all HFEA licensed clinics with an early warning of major clinical incidents to share learning and reduce the risk of similar incidents occurring. It will do much to improve good practice across the field.

Delivering organisational improvement on this scale is not easy. It tests relationships and involves a great deal of determination. I would like to take this opportunity to thank all those who have been involved with the reforms I have described: most obviously our staff and Members, but also our clinic colleagues, patients, professional organisations and those we work closely with at the Department of Health and in Parliament.

The HFEA will continue to be the subject of close, and rightful, scrutiny. We must continue to be a watchdog for patients, a guardian of Parliament's intentions, a supporter of good clinical practice, a protector of disciplined and lawful research and above all a protector of the interests of all those whose births we have celebrated in this special year.



Suzi Leather
Chair

"The HFEA regulates across public and private sector treatment alike and has played an important part in the success of IVF and donor insemination. Strong regulation is absolutely vital to continued public and patient confidence."

Forward Look by the Chief Executive

When I joined the HFEA in November 2002, it was a very challenging time in the organisation's development. Since then, I am pleased to report that the HFEA has made significant progress in implementing its demanding agenda of modernisation and improvement, which has already begun to deliver results.

We have placed particular emphasis on developing our licensing and inspection process both for treatment and research. This has involved a programme of actions including training and evaluating inspectors and adopting more objective tools for inspections. The HFEA has also made considerable progress in ensuring that the application and renewal processes for HFEA licences are faster and more effective. In the coming year we will set higher targets for the timescale of processing inspections and licence applications.

We are actively addressing the past deficiencies of our information system and the Register of clinical activity and offspring. This will ensure that we can meet our statutory responsibilities. Developing our information systems will allow greater flexibility for the future and will support the HFEA, over the longer term, in collecting data from licensed centres electronically. An initial pilot project will begin with a small number of centres in October 2003 with a view to the programme being rolled out to all centres in 2004.

The HFEA is an evolving organisation that works in a complex and rapidly changing environment which generates high levels of scientific, medical, media and public interest. Our wide ranging remit covers policy, regulation, licensing and research, but the key principle that underpins all our work is to ensure the safety and satisfaction of patients using assisted reproductive technology in the UK.

We are committed to engaging more closely with patients and supporting them effectively in the choices they make. Mechanisms are being developed for patient feedback and involvement to be included in the clinic inspection process. In the coming year we will be working with patient groups to develop more comprehensive and meaningful information for a new Patient's Guide in 2004.

The HFEA is also working closely with other professional bodies to develop quality standards for IVF laboratories which will support clinics in meeting the requirements of the Tissue Banking Code of Practice and the European Union Tissue Directive. Our aim is to complete this work by early 2004, well ahead of the directive becoming legally binding in the UK.

The UK has gained recognition for being at the forefront of new reproductive technologies, developed within a framework of effective regulation and governance. This has been achieved through the dedication and commitment of HFEA staff and Members and the Authority's links with key European and international bodies that facilitate shared learning and good practice around the globe.

It is vital that in the coming year, we build on these strong and positive foundations to deliver a more efficient, effective and consistent regulatory service that can keep abreast of this exciting area of scientific advance.

A. McNab

Angela McNab
Chief Executive

Financial Statements
The financial statements on pages 46 to 58, together with the Foreword and other statements on pages 38 to 43 and the Certificate and Report of the Comptroller and Auditor General on pages 44 to 45, reproduce in full those included in the Accounts for the HFEA for 2002-03 laid before the House of Commons on 16th July 2003 under reference HC1017. Pages 1 to 35 of this Annual Report provide additional information, for which I am responsible, that is not included with those Accounts. The Auditor is required by auditing standards to read other information in documents containing audited financial statements and to consider the implications for his audit opinion. A supplementary statement has accordingly been provided by the Comptroller and Auditor General at page 44 in respect of his reading of the additional information.

"The UK has gained recognition for being at the forefront of new reproductive technologies, developed within a framework of effective regulation and governance."

1. About the Human Fertilisation and Embryology Authority

The Human Fertilisation and Embryology Authority (HFEA) was set up in August 1991 by the Human Fertilisation and Embryology Act 1990 (HFE Act). The first statutory body of its type in the world, the HFEA's creation reflected public and professional interest in the potential of human embryo research and infertility treatments, and a widespread desire for statutory regulation of all related procedures.

The HFEA's principal tasks are to license and monitor centres that carry out *in vitro* fertilisation, donor insemination and human embryo research. The HFEA also regulates the storage of gametes (sperm and eggs) and embryos.

The HFEA's statutory functions include

- Producing an HFEA Code of Practice which gives guidelines to clinics about the proper conduct of HFEA licensed activities
- Maintaining a formal register of information about donors, treatments and children born from those treatments
- Providing relevant advice and information to patients, donors and clinics
- Regularly reviewing information about human embryos and any subsequent development of such embryos, and the provision of treatment services and activities governed by the HFE Act

Underlying all these activities is the HFEA's determination to safeguard the interests of patients, children, service providers, scientists and the wider public.

The HFEA's Members and Executive staff

HFEA Members are appointed by UK health ministers in accordance with the guidance from the Commissioner for Public Appointments (The Nolan Guidelines). The Members determine HFEA's policies and review treatment and research licence applications. To ensure that the HFEA has an objective and independent view, the HFE Act requires that the Chair, Deputy Chair and at least half of the HFEA Members are neither doctors nor scientists involved in human embryo research or providing fertility treatment.

Members are not appointed as representatives of different groups, but bring to the HFEA a broad range of expertise, for example medical, scientific, social, legal, managerial, religious and philosophical. (Details of Members' declarable interests are provided in Appendix 6.)

The HFEA's Executive has 84 members of staff who are responsible for implementing the HFEA's policy and licensing decisions and conducting the HFEA's day-to-day activities.

The HFEA Business Plan

The HFEA Business Plan for 2003/04 sets out the way the Authority intends to deliver stronger regulatory procedures in a rapidly changing environment. The most important aim is to ensure that the quality of services for patients undergoing fertility treatment in the UK meets the highest standards. The Business Plan is built upon 10 key objectives for 2003/04 that mark the beginning of a long term programme of improvement in the performance of the Authority and reflects themes set out in the HFEA Corporate Plan.

The key objectives of the HFEA Business Plan 2003/04 are

- To achieve a stronger, more effective and consistent process of regulating fertility services and the storage of gametes and embryos
- To achieve a more comprehensive, open and systematic approach to licensing and regulating research
- To put in place a robust information management strategy and framework
- To improve the quality, range and speed of communication and information for all stakeholders including patients and the general public
- To develop and implement clear policies based on evidence and ethical considerations supporting best clinical practice, underpinning regulation and contributing to the ongoing improvement in standards
- To work in an open and honest way within the boundaries of codes of confidentiality
- To provide valid and comprehensive information for patients and the public
- To ensure through the establishment of clear systems that the HFEA meets its statutory financial and corporate responsibilities demonstrating efficiency, effectiveness and value for money
- To develop and implement a human resource strategy that values staff and to ensure appropriate capacity and skills are developed
- To strengthen partnership working with other statutory and voluntary organisations, including patient groups

The HFEA Corporate Plan

The HFEA Corporate Plan was published in June 2003 to outline the HFEA's strategic aims and objectives for the five years 2004-2009. The plan focuses on the HFEA's core functions: regulation, policy development and communication with patients and the public. The Plan's seven corporate goals which set the direction for the HFEA over the next five years are

- Strengthening the HFEA's regulatory role
- Being an open organisation, through excellent communications and partnership with stakeholders
- Working closely with other regulators and international agencies
- Strengthening the process of HFEA policy development
- Developing an information base which meets the needs of offspring and stakeholders, and the wider regulation and public health functions
- Supporting the development of research in assisted conception, and its application
- Developing an organisation which will fulfil these goals, supported by strong corporate governance

Accounts 2002-2003

During the year the HFEA received income of £5.61m. Full details are set out in pages 38 to 58.

The National Audit Office (NAO) audited these Accounts and the Certificate and Report of the Comptroller and Auditor General is shown on pages 44 to 45. The qualification of the Accounts that had applied to financial years 2000-01 and 2001-02 in respect of the HFEA's inability to verify the completeness of the licence fee income was removed this year. This was achieved as a result of the Authority's own comprehensive

audit of clinic records that was completed in July 2003. This project provided adequate evidence to substantiate the level of income shown in the HFEA's Accounts.

Further details about the actions taken by the HFEA in resolving this issue, the audit work undertaken by the NAO, and the further actions being taken by the HFEA to ensure that billing procedures remain robust and verifiable and fee income collectable from clinics, is set out in the Certificate and Report of the Comptroller and Auditor General.

Membership of the HFEA

Chair
Suzi Leather

Deputy Chair
Professor Tom Baldwin
Professor of Philosophy
University of York

Members

Professor David Barlow
Nuffield Professor of Obstetrics and Gynaecology
University of Oxford, Head of Oxford Fertility Unit

Professor Christopher Barratt
Scientific Director, Birmingham Women's Health Care Assisted Conception Unit

Professor Peter Braude
Head of the Department of Women's Health
Guy's, King's and St Thomas' School of Medicine,
Director of the Centre for Preimplantation Genetic Diagnosis,
Guy's and St Thomas' NHS Trust

Ivor Brecker
General Dental Practitioner (retired)

Clare Brown
Executive Director of CHILD,
The National Infertility Support Network

Professor Iain Cameron
Professor of Obstetrics and Gynaecology
University of Southampton

Jane Denton
Director of the Multiple Birth Foundation
Queen Charlotte's and Chelsea Hospital

Professor Andrew Grubb
Professor of Medical Law and Head of Law School
University of Cardiff

Professor Neva Haites
Professor of Medical Genetics, University of Aberdeen

Emily Jackson
Senior Lecturer in Law, London School of Economics

Dr Maybeth Jamieson
Consultant Embryologist, Assisted Conception Service,
Glasgow Royal Infirmary

Simon Jenkins
Columnist, The Times

Walter Merricks
Chief Ombudsman, Financial Ombudsman Service

Sara Nathan
Freelance broadcaster and producer

The Right Reverend Dr Michael James Nazir-Ali
The Lord Bishop of Rochester

Sharmila Nebhrajani
Chief Operating Officer and Finance Director
BBC New Media and Technology

Senior Staff

Chief Executive
Angela McNab

Director of Regulation
Paul Gemmill

Director of Resources and Corporate Development
Barry MacDonald

Director of Information Management
David Tellis

Director of Policy and Communications
Tim Whitaker

2. Licensing and inspection

Every clinic in the UK that offers IVF or donor insemination (DI) treatment, the storage of gametes (sperm and eggs) or embryos, or that carries out human embryo research, is required by law to be licensed by the HFEA. The licensing process ensures that proper standards are maintained and assists in informing the HFEA about current and developing practice. The licensing process is also a useful mechanism for gathering and disseminating information which helps to raise standards of practice. The tables below show the number and type of centres licensed by the HFEA as of 31 August 2003.

Type of HFEA licensed centre	Number of centres
Treatment only	2
Storage only	8
Treatment with storage	80
Treatment with storage and research	15
Research only	5
Total	110

HFEA licensed treatments	Number of centres
Storage of eggs (including ovarian tissue)	20
Storage of sperm (including testicular tissue)	103
Storage of embryos	76
Donor insemination	96
In vitro fertilisation	75
Intra Cytoplasmic Sperm Injection (ICSI)[1]	74
Preimplantation Genetic Diagnosis (PGD)[2]	8
Preimplantation Genetic Screening for Aneuploidy (PGS)[3]	5

1 ICSI is a type of IVF treatment that involves the injection of a single sperm straight into each egg.

2 PGD is a technique used to detect whether an embryo created *in vitro* is carrying an inherited genetic defect that will give rise to a serious genetic disorder.

3 PGS refers to techniques whereby certain categories of patient, thought to be at a higher than average risk of conceiving an embryo(s), with a sporadic chromosomal abnormality have their embryos tested to determin whether any embryo is affected. The purpose of preimplantation genetic screening for aneuploidy (numerical chromosomal abnormality) is to help those seeking fertility treatment to produce healthy children and to reduce the risk of miscarriage.

The licensing process

The HFEA's Licence Committees make all decisions about HFEA licences, where appropriate seeking external advice. Each Committee is made up of five HFEA Members who determine whether a licence should be granted, suspended, amended or revoked. If a licence is granted, centre specific conditions may be attached to that licence.

The HFEA has made significant achievements in developing its licensing process to ensure that the organisation can effectively respond to the increasing number of licensing applications now and in the future.

The HFEA's continuous programme of improvement will ensure that all licensing decisions reflect current thinking and a consistent approach to decision making is maintained. In addition, the HFEA has recently appointed a dedicated team of staff to support the smooth and efficient running of the Licence Committees and as a result, the overall speed of processing licence applications and renewals has increased.

Forward Look

A key theme for the coming year is to improve patient involvement and have greater transparency in the HFEA's inspection and licensing process. The HFEA will develop a series of pilots to find the most effective way to facilitate patient involvement in licensing and inspections. This may include working with patient groups at centres, devising and issuing patient questionnaires and organising drop-in meetings. Following these pilots, the HFEA will begin fully integrating patient views in the inspection and licensing process by early 2004. This will ensure that the HFEA has the confidence of clinicians, centres and its most important stakeholders, patients.

Outcomes of Licence Committees will be publicly available over the coming year and the HFEA will provide full details of its licensing process on a dedicated website that can be accessed by centres licensed by the HFEA. In addition, the HFEA will also standardise the application of conditions and recommendations from Licence Committees and increase the resources that are put into licensing.

Inspections

The HFEA is committed to continually reviewing and advancing its inspection processes and protocols. These protocols prompt inspectors to cover all relevant areas of compliance whilst encouraging wider discussion of general issues of good practice. The protocols are based on the requirements of the HFE Act, the HFEA and all other relevant professional guidelines.

After a thorough recruitment and assessment process, the HFEA now has 20 new inspectors bringing the total number to 80[4]. A new team of professional regulatory managers have also been recruited and they have completed a rigorous training programme that included shadowing the work of a clinician, counsellor and embryologist at a licensed centre. Regulatory managers chair all inspections and bring greater consistency, professionalism and shared learning to HFEA inspections.

The inspection process links directly into the licensing process. Under the HFEA's three year inspection cycle, every centre that has been granted a three year licence receives an 'interim' inspection each year, before they apply to renew their licence and receive a full inspection. The interim inspections enable the inspection team and subsequent Licence Committee to gather information regarding the centre's current activities. Interim inspections usually have a particular focus that will be determined by the types of treatment offered at the centre, the outcome of previous inspections and/or any issues that have arisen during the year. The interim inspection is also a means for the HFEA to monitor compliance with any conditions or recommendations that a centre may have on its licence, and also with any recent HFEA developments.

In response to feedback from centres, all inspections are now booked six months in advance giving centres, HFEA staff and inspectors sufficient time to prepare and, where possible schedule inspections on days that require minimal disruption to patients. In addition, a programme of unannounced inspections was launched in August 2003 to ensure high standards of treatment are maintained and that adverse incidents are swiftly inspected and managed.

Adverse incidents

Adverse incidents in HFEA licensed centres include any event that causes potential or actual harm to embryos, gametes or patients. This includes breaches of the HFE Act and/or the HFEA Code of Practice. All such incidents should be reported to the HFEA's Regulation Department as soon as they have been discovered. The HFEA assesses the severity of the incident. If a decision is made to send an inspection team to the relevant centre they are usually on-site within 48 hours of notification of the incident. The inspection team then reports back to a Licence Committee, which decides what further action, if any, needs to be taken by the centre. For incidents where an inspection team is not sent immediately, the incident and the centre's response will be investigated at the next formal inspection.

The HFEA is currently piloting a new alert system where anonymised details of incidents are disseminated to all HFEA licensed centres, supported by best practice recommendations from the Authority. This helps to minimise the possibility of the incident occurring at another centre. Initial feedback on the pilot has been very positive and centres welcome this new way of sharing information and best practice. The process has also led to centres identifying more issues that they wish to discuss with the HFEA, further contributing to the process of minimising potential risks.

Forward Look

In the coming year the incident management and alert systems will be formalised within the work of the HFEA Regulation Department. This will be supported by the recruitment of a specialist manager with sole responsibility for incidents, alerts and patient complaints. The alert system will continue to be developed in response to the needs of the sector.

A dedicated website that can be accessed by centres will also collect all the regulatory information a centre needs such as the Code of Practice, the HFE Act and Chair's letters. In addition, the Authority is developing a 'how to' guide for centres which will be piloted shortly and will give centres all the information they need on meeting the Authority's regulatory requirements.

The HFEA will also continue its work developing memorandums of understanding with other regulatory and professional bodies such as the General Medical Council.

[4] A current list of HFEA inspectors, as of 31 August 2003, can be found in Appendix Three.

3. Clinical audit

Annual accounts

In October 2002, the HFEA recruited a team of auditors to verify the reporting of treatments by clinics and the accuracy of billing of fees by the HFEA. The project, which was completed for 2002/03 showed that, in all material respects, all treatments that had occurred had been properly reported to the Authority and had been accurately invoiced. As a result, the qualification of the NAO's opinion on the accounts of financial years 2000/01 and 2001/02 was removed for the financial year 2002/03.

The Register project

Following an intense period of training, and the creation of auditing and reporting protocols, a team of eight qualified auditors visited 90 clinics in the period October 2002 to March 2003. Over these five months, the team examined records of:

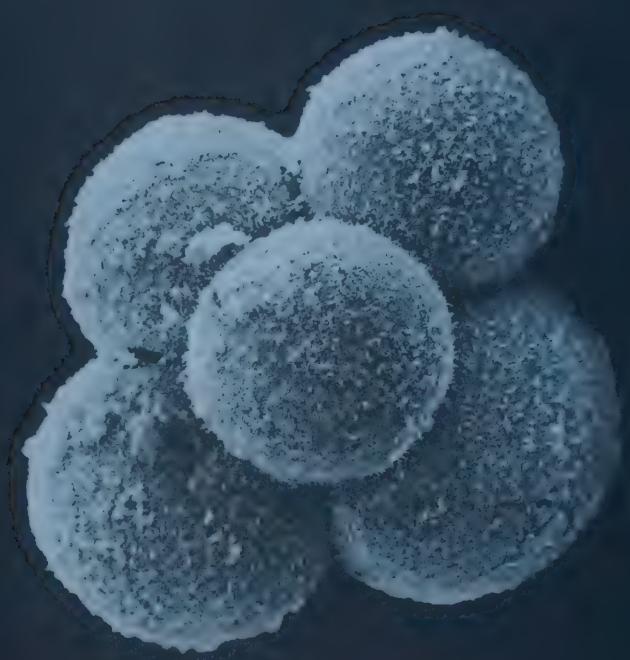
Licensed treatments in 2002/03	4,859
Licensed treatments between 1991-2001	5,775
Live births between 1991-2001	3,988
Patients' files	1,515
Monthly HFEA invoices in 2002/03	900

Over the past year, the HFEA has made considerable progress in developing the audit function and strengthening its procedures to ensure that the HFEA receives complete and accurate information. The audit team has been working closely with the HFEA's registry team to update and verify the information held on the HFEA's Register.

Forward Look

In the future, the audit function will be integrated into the inspection process and will consist of a rolling programme of visits to clinics to ensure the completeness and accuracy of reporting of information.

A historic audit of the data already held in the Register, the scope of which has yet to be decided by the Authority, will also be carried out to ensure optimal accuracy and accessibility of data to meet the future needs of the Authority, patients and their offspring and members of the public.



4. The HFEA Code of Practice

According to the Human Fertilisation and Embryology Act 1990

"The Authority shall maintain a Code of Practice giving guidance about the proper conduct of activities carried out in pursuance of a licence under the Act and the proper discharge of the functions of the person responsible to whom the licence applies."

The Act also indicates that the HFEA should regularly review and update the Code of Practice to ensure that it addresses new and existing areas of clinical and scientific practice in a directive and informative manner. To date, the HFEA has produced five editions of the Code. The fifth and most current edition of the Code was published in June 2001.

The draft sixth edition of the HFEA's Code of Practice was submitted to written consultation in May 2003. The aim of this consultation, which closed in August 2003, was to provide service providers with the opportunity to comment on new sections in the Code and to submit suggestions as to how the Code could be made a more practical and comprehensive document. The HFEA also consulted a wide range of organisations with an interest in assisted reproduction and related practice and research.

The draft sixth edition includes new policy on two embryo transfer, egg sharing, adverse incidents and welfare of the child. The draft also incorporates new sections on preimplantation genetic testing, and witnessing of clinical and laboratory procedures, and updated sections on consent to examination and treatment, research and complaints.

Based on evaluation and analysis of the written responses to the consultation, the HFEA will produce a new edition of the Code of Practice at the end of 2003. This document will be submitted to the Secretary of State for approval and disseminated widely in both print and electronic form.

"The Code of Practice is a fundamental reference document for the HFEA and all HFEA licensed centres around the UK. In turn it affects the services and support that patients receive at these centres, and we very much look forward to the sixth edition of the Code providing comprehensive guidance and support to centres and patients alike." **Suzi Leather, Chair**

5. Research

Embryology research has enormous potential benefits in the understanding and treatment of serious disease and also the development of techniques relating to assisted reproductive technology. The HFEA is uniquely placed to license and regulate this research and provide scientific and ethical standards to existing and proposed research projects in the UK.

The HFE Act requires the HFEA to regulate the creation, storage and use of embryos in research throughout the UK. The Act was amended in 2001 to allow the use of embryos for stem cell research and the HFEA has the responsibility for regulating all research regarding the derivation of embryonic stem cells in the UK.

Under the Act, any research must relate to one or more of the following purposes

- Promoting advances in the treatment of infertility
- Increasing knowledge about the causes of congenital diseases
- Increasing knowledge about the causes of miscarriage
- Developing more effective techniques of contraception
- Developing methods for detecting the presence of genetic or chromosomal abnormalities before implantation
- Increasing knowledge about the development of embryos
- Increasing knowledge about serious disease **or**
- Enabling any such knowledge to be applied in developing treatment for serious disease

Consent from patients donating spare or surplus embryos must specify a statutory research purpose and cannot be used for any other purpose.

The following activities involving human embryos are not permitted under UK legislation

- Keeping or using an embryo after the appearance of a primitive streak or 14 days, whichever is the earlier
- Placing a human embryo in an animal
- Replacing the nucleus of a cell of an embryo with a nucleus taken from the cell of another person, another embryo, or a subsequent development of an embryo
- Altering the genetic structure of any cell while it forms part of an embryo
- Using embryos for any other purposes except in pursuance of a licence

The continuing interest in advancing the science that underpins assisted reproductive technology has seen a gradual increase in the number of research applications and licences. In particular, the number of projects relating to the development of human embryonic stem cells, a major scientific advance for the UK, has doubled in the last year.

Statistics*

- 149 research licence applications have been received by the HFEA since 1991
- 116 research projects have been licensed by the HFEA since 1991
- 26 research projects are currently licensed by the HFEA
- 8 licensed research projects relate to embryonic stem cells
- 1 licensed research project relates to parthenogenesis[5]

* as of 31 August 2003

The research licensing process

Most researchers contact the HFEA to discuss their proposed research before they submit an application. Advice relating to scientific issues is given by the HFEA's policy team and queries on the application process are handled by the HFEA Regulation Department.

The HFEA target for dealing with research applications is three months, with additional time allowed for each application to be peer reviewed. To ensure that all research applications are reviewed in a timely manner, the HFEA plans to strengthen its team of peer reviewers over the coming year.

Until recently, research licence applications were assessed by a general Licence Committee. Licence Committees have statutory responsibilities and are made up of Members of the HFEA. In response to feedback from researchers, centres and others, the HFEA is establishing a dedicated Research Licence Committee to ensure applications are processed in a timely manner. The Committee will consist of five HFEA Members and will have a lay majority and a lay chair. The Committee will meet six to eight times a year and have access to scientific and clinical expertise to support the decision making process.

Research licences are only granted after a thorough and vigorous selection process approved by an external Research Ethics Committee of the organisation concerned. The HFEA's Code of Practice provides guidance on the use and constitution of such Ethics Committees. An application to the HFEA for licensed research must contain a range of information including its objectives, protocols to be used and why the use of sperm, eggs or embryos is necessary.

Completed applications are sent to the HFEA's Regulation Department and a senior regulatory manager will initiate a peer review and contact the applicants to arrange a site visit. HFEA peer reviewers[6] will be asked to determine whether the application

- Comes within the statutory purposes of the 1990 Act (as amended)
- Requires human embryos to fulfil its aims and objectives
- Requires the numbers and types of embryos outlined in the application
- Meets the requirements of the HFEA Code of Practice including ethical approval and patient information

Once peer review has been obtained, researchers may be asked to respond to comments. When a satisfactory response has been received a site visit will normally be undertaken by an HFEA senior regulatory manager, the HFEA regulatory officer for the centre concerned and, in most cases, an independent scientific inspector. The primary focus of this visit is to meet the research staff, inspect the research laboratories and gain a greater understanding of the project and its protocols.

Applicants will have an opportunity to see the inspection report and comment on any issues of factual accuracy before it goes to a Licence Committee for a decision. The Licence Committee may require further work before it is prepared to grant a licence or it may reject an application. In these circumstances the applicant has a statutory right to appeal. Research licences are

usually granted for up to three years and the Licence Committee has the power to make additional conditions and/or recommendations on the licence being granted.

All licensed research projects must produce a progress report for the HFEA every six or 12 months. At the end of the research project, the researchers must produce a final report for the HFEA containing the results and conclusions of the project and references to any publications resulting from the work.

Over the last year, the HFEA has carried out a great deal of work to improve its research licensing process. The HFEA has maintained and developed its close working relationships with relevant bodies including the Medical Research Council and the Medicines and Healthcare products Regulatory Agency. In addition, a dedicated team of staff to manage the Authority's work in the research field has recently been recruited.

[5] Parthenogenesis is the process by which eggs are artificially stimulated causing them to divide and behave in a similar way to standard embryos, but without being fertilised by sperm. These cells do not have the potential to develop into a child.

[6] A current list of HFEA peer reviewers, as of 31 August 2003, can be found in Appendix 5.

Forward Look

In the coming year, the HFEA will develop a section of its new website clearly detailing the complete research application process. Plans are also underway to provide summaries of all licensed research projects on the HFEA website. Additionally, the HFEA will begin a review of the fee structure for research licence applications and continue its work in developing and refining the work of the Research Licence Committee to ensure that it can effectively and efficiently meet the demands placed upon it.

In November 2003, the HFEA will invite all centres that have current and past research licences and other stakeholders to participate in a full day conference to discuss the current state of embryo research across the UK.

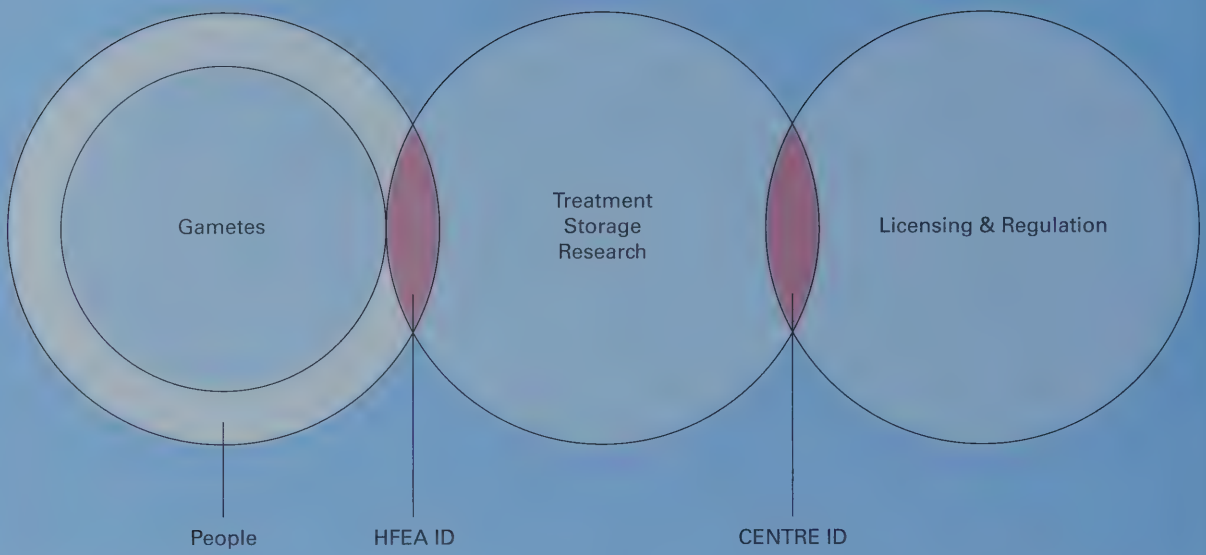


Figure One

6. Information technology and data collection

The HFEA Register

The HFEA has a duty to store all registrations, treatments and outcomes that result from assisted reproductive techniques on a 'register'. The HFEA Register contains details of licensed treatments and donor characteristics for the whole of the UK and is the largest database of its kind in the world. IT systems developed in past years have given rise to problems over accuracy and access to data in the Register.

During 2002/03 a modern flexible database system was successfully developed and implemented and transfer of data from previous systems will take place shortly. A programme is planned to check previous data and resolve any inaccuracies. This will ensure the Register is able to meet the HFEA's statutory duties.

The licensing and regulation database

A new IT system (known internally as the Centres Database) which was developed to support the licensing and regulation activity, was implemented in July 2003. This system integrates closely with the new Register system.

The structure

Figure One shows the overall structure of the new HFEA systems. On the right-hand side of the diagram are the licensing and regulation tables which include:

- Centre names, addresses and staff
- Licensed activities, conditions/directions and recommendations
- Inspection visit details and incidents
- HFEA staff, Members and inspectors

The middle and left-hand side of Figure One represents

- People (patients, partners and donors)
- People registrations
- Gametes
- Treatments
- Pregnancy outcomes

Because of the sensitivity of the information which is held, and the need to produce a wide range of statistical reports relating to treatments and outcomes, details about people and their gametes are held in separate tables from the treatments and outcomes. A unique counter reference is assigned to each individual (called the HFEA ID) that is used to anonymise the data held in the live registration, treatment and outcome tables, as shown in Figure Two.

To meet its statutory requirement for a register of treatments and outcomes, the HFEA is currently using paper based forms to obtain information from licensed centres on patient and

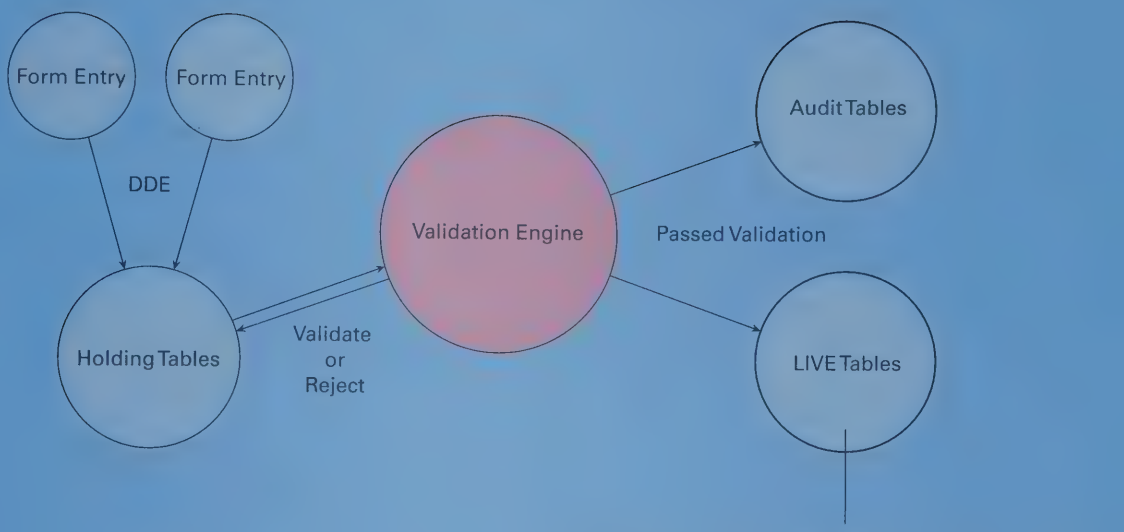


Figure Two

partner registration, donor information, donor gamete treatment, IVF treatment, embryo creation and use and pregnancy outcomes.

The HFEA has made significant progress in modernising its systems and HFEA staff are already engaged in a large, complex programme of work that will allow the current paper based forms to be collected electronically. Electronic Data Interchange (EDI) will begin in 2004. The HFEA is also working closely with licensed centres to ensure this important information can be shared between compatible systems in a secure and confidential way.

During this vital period of modernisation and transition, the HFEA has put in place a number of interim measures including double data entry (DDE) to ensure that paper forms are entered onto the computerised system by two operators and run through a matching process to identify any discrepancies. This process, shown in Figure Two, was introduced in February 2003 to eliminate manual keying errors. Once both entries match, they are picked up by a validation engine which runs a series of important checks that includes verifying that treatments carried out at individual centres are appropriately licensed and within specified limitations. Time and effort has been spent ensuring that the new systems are entirely secure.

Summary of Achievements

The HFEA has made considerable progress over the last year in developing and implementing this large scale IT modernisation project. The HFEA has successfully completed phases one and two of this three phase plan which includes

- The development of the licensing and monitoring database to significantly enhance the licensing, monitoring, inspection booking, tracking and outcome process to allow greater workflow control
- The development of the Register Database including the use of double data entry and data validation engine programmes to reduce errors introduced into the system.

The new system is being built on a robust software and hardware platform which can easily cope with the performance demands placed upon it. The system allows a great deal of flexibility for the future to cope with the ever changing needs of the HFEA and its various stakeholders.

Forward Look

In future, the system will be able to provide real information from the volumes of data that the HFEA already has and continues to collect on a daily basis. Initially the majority of reports will be for internal management purposes but ultimately reports which are useful to both patients and centres will become widely available through the HFEA website. The HFEA plans to support patients with clear and accurate information about treatments, services and outcomes by December 2004.

7. Communications

Communicating with patients, donors, the media, clinicians, Government and the general public is a vital part of the HFEA's work. Under the terms of the HFE Act, the HFEA has a duty "to publicise the services provided to the public by the HFEA or provided in pursuance of licences" and provide "advice and information for persons to whom licences apply or who are receiving treatment services or providing gametes or embryos for use...or may wish to do so".

As public and media interest in assisted reproductive technology and stem cell research continues to grow, the HFEA is committed to continuously improving the quality, range and speed of communication to all those with an interest in its work.

Media work

The HFEA continues to have a high profile in the press. Through press releases and background briefings, staff in the HFEA press office worked closely with print and broadcast journalists to provide fast and accurate information across the whole range of HFEA activities in 2002-2003.

The press office receives more than 120 calls and emails from journalists each week seeking information or comment on issues relating to law and policy, research, service provision, new assisted conception techniques and questions about individual clinics. The HFEA is recognised worldwide because of the advanced state of regulation in the UK and the press office regularly handles calls from overseas journalists.

When a new clinical development or an adverse incident is of interest to the media, the press office works closely with clinicians, the Department of Health and other interested parties to ensure that accurate information is given to the media without compromising patient anonymity.

In response to a steady stream of requests from the media, educational institutions, professional bodies and patient groups, the HFEA regularly provides speakers for national and international conferences and interviewees for newspapers, magazines, radio and television. In addition, HFEA Members and staff continue to write articles for mainstream, specialist and patient publications.

Information and resources for patients

Every week, the HFEA receives a large number of calls from patients requesting HFEA publications or seeking advice and information on fertility treatment. From January to July 2003, the HFEA dealt with over 3,000 requests from patients for information.

In April 2003, stakeholder meetings provided important feedback to the HFEA on the style and type of information that would be most useful for patients. Since the meeting, the HFEA has designed a new series of patient leaflets which provide guidance and advice on egg and sperm donation, ICSI, consent to the use and storage of gametes and embryos and welfare of the child.

In addition, an HFEA sponsored questionnaire which was co-ordinated by the patient support group CHILD indicated that individuals and couples still want more information about assisted reproductive services and support systems for patients in the UK. Over the coming months, the HFEA will continue working with CHILD and other patient groups to ensure patient feedback and recommendations are incorporated into the development of HFEA patient and public information.

In August 2003, the HFEA launched a new website with a clinic search facility for patients, a new section dedicated to HFEA licensed research and a glossary of medical terms and advice for donors. The website has been developed to satisfy the needs of a diverse audience and can now provide answers to a greater variety of general and specific information requests. Between January and June 2003, the HFEA website received 1,534,884 hits and was accessed by 45,142 individuals.

Meetings and conferences

The HFEA is constantly expanding its communication programmes, making every effort to engage, and seek the opinion of the general public, individuals and professionals about its role in regulating fertility treatment. With this in mind, the HFEA has increased its collaboration with professional groups and stakeholders including the Association of Clinical Embryologists (ACE), the British Fertility Society (BFS), the Royal College of Obstetricians and Gynaecologists (RCOG), the NHS Confederation, the Commission for Health Improvement and the National Care Standards Commission.

In December 2002, the HFEA was invited to the House of Commons by the Science and Technology Committee to launch its public consultation on sex selection. The event was attended by politicians, peers, patient groups and interested professionals and provided a forum for an informed discussion and debate. The outcome of the public consultation and the HFEA's advice to Government will be published by the HFEA at the end of 2003.

In January 2003, the then Parliamentary Under Secretary of State for Public Health Hazel Blears opened the HFEA's Annual Conference in London. The conference, which included presentations and discussions on regulating research, definitions of treatment cycles and ensuring the HFEA's improved performance, was attended by over 200 delegates.

At the end of March 2003, the HFEA organised a conference for licensed centres to discuss the new edition of the HFEA Code of Practice. As a result of this conference, and the valuable contributions of the centre staff and clinicians who attended, the HFEA decided to submit the draft sixth edition of the Code to written public consultation. A new edition of the Code will be produced at the end of 2003.

Throughout the year, HFEA Members and staff regularly gave talks and presentations at a number of seminars, conferences and events. A highlight, in July 2003 was a conference celebrating 25 years of assisted reproduction in the UK hosted by the Royal College of Obstetricians and Gynaecologists, where HFEA Chair Suzi Leather gave a speech on the impact of regulation on IVF practice.

The HFEA is working towards becoming a more open and accessible organisation and, in October 2003, the decision-making body of 18 Members will meet for the first time in public.

The HFEA is constantly expanding its communication programmes, making every effort to engage, and seek the opinion of the general public, individuals and professionals about its role in regulating fertility treatment

Forward Look
The HFEA is currently developing a communications strategy which will set clear objectives for communications activities to meet the needs of HFEA stakeholders and audiences. This strategy recognises the need for the HFEA to remain an accountable and open public body and to work with other organisations to ensure that patient, service provider, public and media interests are maintained and promoted in the UK and in other countries where assisted conception is not – as yet – regulated to the standards set in the UK.

Policy update

The HFEA policy team works closely with other HFEA departments, HFEA Members and Committees, and external agencies to assess current and future needs relating to policy analysis and development. These policies relate to the duties of the HFEA under the HFE Act. Where appropriate, the HFEA advises the Secretary of State on proposed policy changes and amendments.

Sex selection

Throughout 2002/03 the HFEA has been conducting a review of sex selection, including new techniques for sorting sperm currently undergoing trials in the United States.

The HFEA last consulted on sex selection in 1993 and consequently confirmed its policy of permitting sex selection using licensed techniques for medical reasons only. Since then the range, sophistication and effectiveness of available techniques has increased significantly. Public awareness of issues surrounding assisted conception has also increased. As well as the use of preimplantation genetic diagnosis to select embryos created *in vitro*, methods exist where sperm are sorted according to whether they carry male or female chromosomes to a level of efficiency that allows samples to be used for artificial insemination with up to 95% reliability in achieving the intended outcome. Techniques of this sort, which avoid the need for intrusive IVF procedures and the creation of large number of embryos, are not currently regulated in the UK. The focus of the consultation was whether these techniques should be regulated and under what circumstances they should be made available.

The review began in early 2002 with literature reviews on the scientific, technical, social and ethical aspects of sex selection practice. This was followed by independent market research involving discussion groups to identify the issues and questions about sex selection that raised the greatest concerns. This research informed the development of an HFEA consultation document, published in October 2002, entitled Sex Selection: Choice And Responsibility In Human Reproduction. The consultation ran from October 2002 to January 2003 and was open to all UK residents. This was supported by an opinion poll commissioned by MORI which canvassed the views of a representative sample of 2000 members of the public.

The response to the consultation was extremely encouraging and over 700 responses were received. A report on the review, including advice to UK health ministers on options for legislation, will be published by the HFEA at the end of 2003.

Donor anonymity and information

In December 2001, the Department of Health launched its consultation on Providing Information about Sperm, Egg and Embryo Donors. The purpose of the consultation was to seek the views of the public about what information should be provided from the HFEA Register to offspring conceived using donated gametes about the donors who provided those gametes.

As present information about donors can only be provided to two categories of person

- Those aged 18 or over may apply to the HFEA to learn whether the information recorded on the HFEA Register shows whether they were conceived using donor gametes
- Those intending to marry, including those who wish to marry before their 18th birthday, can apply to find out whether the information recorded on the HFEA Register shows whether they are or might be related to the person whom they intend to marry

Although no other information about the gamete donors can currently be provided, Parliament has the power to permit additional non-identifying information held by the HFEA to be given to applicants aged 18 or over, with the possibility that in the future identifying information could be given about donors after the regulations come into force. These provisions apply to those born as a result of treatment services provided on or after 1 August 1991, when the HFEA began recording information. Licensed clinics can currently provide non-identifying information about donors with the consent of the person who received treatment.

In its response to the Department of Health consultation in July 2002, the HFEA expressed the view that whilst anonymity should not be removed from those who have previously donated gametes on the understanding that their anonymity would be protected, and notwithstanding a possible decline in donor recruitment, the welfare of offspring requires that in the future all donor offspring should have the right to know the identity of the donors used in their conception.

The HFEA advised that regulations should be made to allow identifying information about those donating gametes or embryos after the regulations come into force to be made available to applicants aged 18 or over. The HFEA's full response can be found on the HFEA website at www.hfea.gov.uk. At the HFEA Annual Conference in January 2003, the then Parliamentary Under Secretary of State For Public Health Hazel Blears, announced that there would be an additional six month review period in order to gather additional information before the Government's legislative intentions were announced.

Stem cells from human embryos

The introduction of the Human Fertilisation and Embryology (Research Purposes) Regulations in 2001 extended the purposes for which the HFEA could licence research using human embryos to include

- Increasing knowledge about the development of embryos
- Increasing knowledge about serious disease
- Enabling any such knowledge to be applied in developing treatments for serious disease

Since the introduction of these regulations the HFEA has licensed eight projects which involve the use of embryos to derive stem cells. The protocols approved will create embryonic stem cell lines from embryos originally created for IVF treatment but subsequently donated for research. The cell lines will be used to increase knowledge of embryo development and to enable such knowledge to be applied in developing treatments for serious disease.

It is a condition of all licences that a sample of all embryonic stem cell lines be placed in the MRC Stem Cell Bank. The Stem Cell Bank operates under the control of a high level Steering Committee consisting of medical and scientific members, ethicists and consumer representatives. The Committee will regulate the use of embryonic stem cell lines and develop codes of practice for the stem cell bank and for the use of stem cell lines. The existence of the bank will also ensure that the use of embryos in research is minimised.

HFEA/MRC working group on follow-up studies

The HFEA considers follow-up studies to be extremely important and has asked the Medical Research Council for advice on the scientific evidence of risks to children born as a result of assisted reproductive technology.

The primary reason for this approach was concern that the results of a small study of patients had potentially linked the use of ICSI with certain genetic and developmental defects. More extensive studies are required to gain further information into these possible effects.

As a result, a joint MRC/HFEA working group was set up in September 2002 to look at the broad area of assisted reproduction including what is already known from biological studies. This group will advise and set priorities on the type of research needed that may range from surveillance, epidemiology and data collection to biological mechanisms and hypotheses.

Patient screening and safe cryostorage

In 2001, the HFEA published a revised policy on patient screening and the safe cryopreservation of human gametes and embryos.

This policy was the result of an HFEA consultation and the recommendations of a multidisciplinary working group made up of HFEA Members and representatives of professional organisations including ACE, BFS and the British Andrology Society (BAS).

The policy aims to reduce the risk of cross contamination between stored gametes and embryos. By December 2004, all licensed treatment and storage centres will be required to undertake the routine screening of all patients for Hepatitis B, Hepatitis C and HIV as outlined in the ACE guidelines. Centres that wish to undertake storage will also need separate storage vessels for infected, uninfected and unscreened samples. These requirements will be incorporated into the sixth edition of the HFEA Code of Practice due for publication in late 2003.

During 2002, the HFEA reviewed this policy in the light of queries raised by licensed treatment and storage centres. This review has included consulting external experts and reviewing best practice in this and related fields. As a result, the HFEA is producing further guidance for clinics on meeting the requirements of the policy which will be disseminated in 2004.

Use of HFEA data for research

The HFEA maintains a Register of data on all cycles of licensed treatment. This allows the HFEA to keep under review information about embryos, any subsequent development of embryos, and the provision of treatment services and activities governed by the HFE Act. Therefore, the HFEA supports and values the use of the data stored on its Register in studies that would inform patients and clinicians on best clinical practice.

The HFEA has a statutory obligation to collect and store information on licensed fertility treatments, but the disclosure of this information is regulated through the HFE Act 1990. Even though the HFEA may disclose information providing that no individual to whom the information relates can be identified, it must ensure any use of this information is appropriate. Any proposal to have access to data from the HFEA Register for research purposes is given careful consideration by the HFEA. As part of the process researchers must demonstrate through peer review or experience that the proposed study is capable of withstanding scientific and academic scrutiny.

Appendix One

p of HFEA Committees and working groups
August 2003)

Audit
The HFEA's Audit Committee meets up to six times a year to review and evaluate policies for ensuring that there is compliance with relevant regulatory, legal and code of conduct requirements as set out in the Controls Assurance Standards and other relevant guidance.

Chair: Walter Merricks
- Jane Denton
- Emily Jackson
- Simon Jenkins
- Luke March (co-opted member)

Ethics and Law Committee
The HFEA's Ethics and Law Committee meets four times a year to review social, ethical and legal issues arising from, or affecting activities in which the HFEA has an interest.

Chair: The Right Reverend Dr Michael James Nazir-Ali
- Professor Tom Baldwin
- Professor Christopher Barratt
- Ivor Brecker
- Professor Andrew Grubb
- Simon Jenkins
- Suzi Leather
- Walter Merricks
- Sara Nathan
- Two or more co-opted members

Information Management Programme Board
The HFEA's Information Management Programme Board currently meets every month to review progress on the development of the HFEA Register.

Chair: Angela McNab (HFEA Executive)
- Professor David Barlow
- Professor Peter Braude
- Steve Carroll (co-opted member)
- Jane Denton
- Professor Neva Haites
- Mark Kinsella (HFEA Executive)
- Suzi Leather
- Barry MacDonald (HFEA Executive)
- Sharmila Nebhrajani
- David Tellis (HFEA Executive)
- Liz Woodeson (Department of Health)

Licensing and Regulation Committee
The HFEA's Licensing and Regulation Committee meets four to six times a year to oversee the work of the HFEA in relation to the licensing and inspection of treatment, storage and research facilities, and the operation of the HFEA.

Chair: Sharmila Nebhrajani
- Professor David Barlow
- Ivor Brecker
- Clare Brown
- Professor Iain Cameron
- Dr Maybeth Jamieson

Organisation and Finance Committee
The HFEA's Organisation and Finance Committee meets up to six times a year to monitor income and expenditure and the arrangements for charging fees to licensed centres.

Chair: Suzi Leather
- Professor Tom Baldwin
- Ivor Brecker
- Professor Neva Haites
- Sharmila Nebhrajani

Scientific and Clinical Advances Group
The HFEA's Scientific and Clinical Advances Group meets four to six times a year to review scientific and clinical developments affecting activities in which the HFEA has an interest, and provides recommendations about this development to inform HFEA policy formulation.

Chair: Professor Christopher Barratt
- Professor Tom Baldwin
- Professor David Barlow
- Professor Peter Braude
- Clare Brown
- Professor Iain Cameron
- Jane Denton
- Professor Neva Haites
- Dr Maybeth Jamieson
- Sara Nathan
- Professor Roger Pedersen (co-opted member)

Liz Woodeson acts as the Department of Health's observer at HFEA meetings.

Appendix Two

Centres licensed by the HFEA
(as of 31 August 2003)

East Midlands

HFEA centre number	Centre name	Location
0068	Assisted Conception Unit	Leicester Royal Infirmary, Leicester
0101	CARE at the Park Hospital	Nottingham
0016	CARE at the Three Shires Hospital	Northampton
0149	Fertility Unit	Derby City General Hospital, Derby
0069	Middle England Fertility Centre	BUPA Hospital Leicester
0076	NURTURE	Nottingham
0162	Queens Medical Centre Fertility Unit	Nottingham

East of England

HFEA centre number	Centre name	Location
0100	Bourn Hall Clinic	Cambridge
0165	Brentwood Fertility Centre	Brentwood
0002	Fertility Clinic	Watford General Hospital, Watford
0188	Isis Fertility Centre	Colchester
0190	Sub Fertility Unit	James Paget Healthcare NHS Trust, Gorleston on Sea
0178	The Fertility Unit	Peterborough District Hospital, Peterborough
0051	University Department of Obstetrics and Gynaecology	The Rosie Hospital, Cambridge

London

HFEA centre number	Centre name	Location
0138	North East London Fertility Services	Ilford
*0080	Andrology Unit	The Hammersmith Hospital, London
0158	Assisted Conception Unit	Chelsea and Westminster Hospital, London
0102	Assisted Conception Unit	Guys Hospital, London
0109	Assisted Conception Unit	King's College Hospital, London
0044	Assisted Conception Unit	University College Hospital, London
0157	Assisted Reproduction and Gynaecology Centre	London
0094	Barts and the London Fertility Centre	London
*0171	Bridge Centre Cryoservices	London
0199	CRM London	London
0074	Cromwell IVF and Fertility Centre	London
0048	Department of Obstetrics and Gynaecology	West Middlesex University Hospital, Isleworth
*0177	Diana Princess of Wales Centre for Reproductive Medicine	London
0030	Essex Fertility Centre	Essex
0163	Fertility Treatment Centre	Shirley Oaks Hospital, Croydon
0153	Fertility Unit	Homerton University Hospital NHS Trust, London
0143	London Female and Male Fertility Centre	London
0088	London Fertility Centre	London
0105	London Women's Clinic/ Hallam Medical Centre	London
0011	Louis Hughes	London
0206	Reproductive Genetics Institute	London
0167	Reproductive Medicine Unit	University College London Hospitals, London
0160	Seymour Clinic	St Mary's Hospital, London
0070	The Bridge Centre	London
0187	The Harley Street Clinic	London
0186	The Harley Street Fertility Centre	London
0006	The Lister Fertility Clinic	London
0078	Wolfson Family Clinic	The Hammersmith Hospital, London

North East England

tre number	Centre name	Location
0170	Centre for Assisted Reproduction	Queen Elizabeth Hospital, Gateshead
0056	Cleveland Gynaecology and Fertility Centre	Middlesbrough
0075	Cromwell IVF and Fertility Centre	Darlington
0055	Department of Reproductive Medicine	James Cook University Hospital, Middlesbrough
0168	Fertility Centre	Bishop Auckland Hospital, Bishop Auckland
0017	Newcastle Fertility Centre at Life	Newcastle upon Tyne
0096	Sunderland Fertility Centre	Sunderland
0031	The Cameron Unit	Hartlepool General Hospital, Hartlepool

North West England

tre number	Centre name	Location
0116	Assisted Conception Unit	Billinge Hospital, Wigan
0025	Assisted Conception Unit	University Hospital Aintree, Liverpool
0185	CARE at the Alexandra Victoria Park	Manchester
0071	CARE at The Wirral Fertility Centre	Wirral
0189	Department of Medical Oncology	Christie Hospital NHS Trust, Manchester
0007	Hewitt Centre for Reproductive Medicine	Liverpool Women's Hospital, Liverpool
0033	Manchester Fertility Services Ltd	Manchester
0067	Regional IVF and DI Unit	St Mary's Hospital, Manchester

Northern Ireland

HFEA centre number	Centre name	Location
0200	Origin Fertility Care	Belfast
0077	Regional Fertility Centre	Belfast

Scotland

HFEA centre number	Centre name	Location
0112	Andrology Laboratory	Western General Hospital NHS Trust, Edinburgh
0115	Assisted Conception Services Unit	Glasgow Nuffield Hospital, Glasgow
0037	Assisted Conception Services Unit	Glasgow Royal Infirmary, Glasgow
0004	Assisted Conception Unit	Ninewells Hospital, Dundee
0019	Assisted Reproduction Unit	University of Aberdeen, Aberdeen
0201	Edinburgh Assisted Conception Unit	Royal Infirmary of Edinburgh, Edinburgh
0098	Infertility Department	Lanarkshire Acute Hospital NHS Trust, Lanarkshire

South East England

HFEA centre number	Centre name	Location
0144	Assisted Conception Services	The Woking Nuffield Hospital, Woking
0015	Assisted Conception Unit	Esperance Private Hospital, Eastbourne
0086	BMI Chelsfield Park ACU	Orpington
0159	Department of Cytopathology	Royal Surrey County Hospital, Guildford
0035	Oxford Fertility Unit	Oxford
0117	Queen Mary's Hospital	Sidcup, Kent
0161	The Brabourne Suite	BMI The Chaucer Hospital, Canterbury
0064	The Chiltern Hospital Fertility Services Unit	Great Missenden
0057	Wessex Fertility Unit	BUPA Hospital Southampton
0121	Wessex Fertility Unit	Princess Anne Hospital, Southampton
0180	Willow Suite	Thames Valley Nuffield Hospital, Nr Slough

South West England

centre number	Centre name	Location
0139	Bath Assisted Conception Clinic	Bath
0024	Centre for Reproductive Medicine	University of Bristol, Bristol
0032	Cotswold Centre	Southmead Hospital, Bristol
0151	Department of Microbiology	Gloucestershire Hospitals NHS Trust, Cheltenham
0005	Peninsular Centre for Reproductive Medicine	Exeter
0197	Salisbury Fertility Centre	Salisbury
0179	South West Centre for Reproductive Medicine	Plymouth
0133	The Winterbourne Hospital	Dorchester
0010	Tower House Clinic	Bristol
0176	University of Bristol	Division of Obstetrics and Gynaecology, Bristol

Wales

HFEA centre number	Centre name	Location
0049	Cardiff Assisted Reproduction Unit	University Hospital of Wales, Cardiff
0059	Cromwell IVF and Fertility Centre	Swansea
*0152	Microbiology Department	Singleton Hospital, Swansea
*0130	North West Wales Fertility Centre	Gwynedd

West Midlands

HFEA centre number	Centre name	Location
0119	Assisted Conception Unit	Birmingham Women's Hospital, Birmingham
0184	Burton Centre for Reproductive Medicine	Burton Hospitals NHS Trust, Burton upon Trent
0013	Centre for Reproductive Medicine	Coventry
0026	Fertility Centre	BMI Priory Hospital, Birmingham
0181	Lifestyle	Sandy Lane Clinic, Newcastle-under-Lyme
0008	Midland Fertility Services	Aldridge
0148	Shropshire and Mid-Wales Fertility Centre	Shrewsbury
0198	St Jude's Clinic for Fertility and Gynaecology	Wolverhampton

Yorkshire and the Humber

HFEA centre number	Centre name	Location
0063	Assisted Conception Unit	St James' University Hospital, Leeds
0061	CARE at The Sheffield Fertility Centre	Sheffield
0196	Centre for Reproductive Medicine and Fertility	Sheffield Teaching Hospitals, Sheffield
0021	Hull IVF Unit	Hull
0052	Reproductive Medicine Unit	Clarendon Wing, Leeds

Research Centres

North West England

HFEA centre number	Centre name	Location
0175	Biological Sciences	University of Manchester, Manchester Research

Scotland

HFEA centre number	Centre name	Location
0166	Institute for Stem Cell Research	Edinburgh Research
0202	Roslin Institute	Scotland Research

Yorkshire and the Humber

HFEA centre number	Centre name	Location
0191	Section of Reproductive and Developmental Medicine	Sheffield Research
0062	University of York	York Research

* Storage of gametes and/or embryos only

Appendix Three

...ectors (as of 31 August 2003)

Mr Masoud Afnan
Consultant Obstetrician and Gynaecologist
Honorary Senior Lecturer
Director of ACU Birmingham Women's Hospital

Mr Bernard Bentick
Consultant Obstetrician and Gynaecologist
Royal Shrewsbury Hospital NHS Trust

Mr Peter Brinsden
Medical Director
Department of Obstetrics and Gynaecology
Bourn Hall Clinic/Cambridge University

Mr Chris Chandler
Consultant Obstetrician and Gynaecologist and Clinical Director
Billing Hospital, Wigan

Dr Ruth Curson
Associate Specialist
King's College Hospital, London

Dr Melanie Davies
Consultant Obstetrician and Gynaecologist
University College London Hospitals

Mr Robert Forman
Medical Director
CRM London

Dr Mark Hamilton
Consultant Obstetrician and Gynaecologist
and Clinical Senior Lecturer
University Of Aberdeen

Dr Stewart Irvine
Consultant/Clinical Scientist
MRC Human Reproductive Sciences Unit, Edinburgh

Mr Richard Kennedy
Consultant Obstetrician and Gynaecologist
Walsgrave Hospital, Coventry

Mr Yacoub Khalaf
Subspecialty Consultant in Reproductive Medicine
Guy's and St Thomas' Hospitals Trust, London

Mr Charles Kingsland
Consultant Obstetrician and Gynaecologist and Honorary Lecturer
The Women's Hospital, Liverpool

Dr Gillian Lockwood
Medical Director
Midland Fertility Services

Mr Stephen Maguiness
Consultant and Honorary Senior Lecturer
Obstetrics and Gynaecology, Hull Royal Infirmary

Mr Mohamed Menabawey
Consultant Obstetrician and Gynaecologist
University Hospital of Hartlepool

Dr John Mills
Consultant Obstetrician and Gynaecologist
Ninewells Hospital, Dundee

Professor Alison Murdoch
Consultant Obstetrician and Gynaecologist
Honorary Senior Lecturer and Director of the
Centre for Reproductive Medicine,
International Centre for Life, Newcastle upon Tyne

Mr Roger Neuberg
Consultant Obstetrician and Gynaecologist and
Director of Infertility Service
Leicester Royal Infirmary, Co-Director BUPA, Leicester

Mr Julian Pampiglione
Consultant Obstetrician and Gynaecologist
The Royal Bournemouth Hospital

Mr John Parsons
Senior Lecturer and Honorary Consultant
King's College Hospital, London

Dr Elizabeth Pease
Consultant
St Mary's Hospital, Manchester

Mr Nigel Perks
Consultant Obstetrician and Gynaecologist
Queen Elizabeth Hospital, Woolwich

Dr David Polson
Consultant Obstetrician and Gynaecologist
Salford Royal IVF and Fertility Centre

Mr Nagy Rafla
Consultant Obstetrician and Gynaecologist
Chaucer Hospital, Canterbury

Mr Andrew Riddle
Consultant Obstetrician and Gynaecologist
Frimley Park Hospital NHS Trust, Camberley

Mr Robert Sawers
Consultant Obstetrician and Gynaecologist
and Programme Director
BMI Priory Hospital, Edgbaston

Mr Eric Simons
Medical Director
Cromwell Hospital, London

Dr Alison Taylor
Consultant in Gynaecology and Reproductive
Medicine and Senior Lecturer
Guy's and St Thomas' Hospitals Trust, London

Dr K. Joo Thong
Consultant
Assisted Conception Programme
Edinburgh Assisted Conception Unit

Mr Peter Wardle
Consultant and Senior Lecturer in Obstetrics and Gynaecology
Southmead Hospital, Bristol

Dr Christine West
Consultant Obstetrician and Gynaecologist
Royal Infirmary, Edinburgh

Dr Robin Yates
Medical Research Director
Assisted Conception Unit, Royal Infirmary, Glasgow

Scientific

Dr Virginia Bolton
Senior Lecturer
King's College Hospital, London

Dr John Clarke
Retired Lecturer in Zoology
University of Oxford

Dr John Coutts
Retired reader in Reproductive Endocrinology

Mrs Jane Cuthbert
Fertility Centre Manger and Senior Embryologist
BMI Priory Hospital, Edgbaston

Ms Karin J Dawson
Consultant Embryologist
Hammersmith Hospital, London

Dr Simon Fishel
Managing Director
Centres for Assisted Reproduction (CARE) Ltd,
Park Hospital, Arnold, Nottingham

Professor Tom Fleming
Professor
Cell Science Division
School of Biological Sciences
University of Southampton

Professor Stephen Franks
Professor of Reproductive Endocrinology
St Mary's ICSM Campus, London

Professor Lynn Fraser
Professor of Reproductive Biology
King's College, London

Dr Ceinwen Gearon
IVF Laboratory Director
Lister Hospital, London

Mr David Gibbon
Senior Embryologist
South Cleveland Hospital

Dr Geraldine Hartshorne
Scientific Director
Centre for Reproductive Medicine, Coventry

Dr John Keith
Senior Scientist
Edinburgh Assisted Conception Unit

Mr Terry Leonard
Co-Director
Isis Fertility Centre, Colchester

Mr Stephen Lynch
Senior Embryologist and Person Responsible
BMI Chaucer Hospital, Canterbury

*Dr Alan McDermott
Director
Regional Cytogenetics Centre, Southmead Hospital,
Bristol

Dr David Morroll
Senior Clinical Embryologist
NURTURE, Nottingham

Dr Lynne Nice
Fertility Services Manager
BMI Chiltern Hospital, Great Missenden

Dr Allan Pacey
Senior Lecturer in Andrology
University of Sheffield

Mr Damian Pike
Senior Embryologist
Woking Nuffield Hospital ACS Unit

Ms Barbara Ray
Principal Embryologist
Centre for Reproductive Medicine, Bristol

Dr John Robinson
Scientific Director
Hull IVF Programme, Princess Royal Hospital, Hull

Reverend Professor Mary Seller
Professor of Development Genetics
Medical and Molecular Genetics, Guy's Hospital London

*Dr Arasaratnam Srikantharajah
Research Embryologist
University Of Aberdeen

*Dr Stephen Troup
Scientific Director
Liverpool Women's Hospital

* denotes ICSI practitioner inspectors

Dr Karen Turner
Clinical Laboratory Director
Oxford Fertility Unit

Dr Maureen Wood
Scientist
University Of Aberdeen

Dr Anick De Vos
Clinical Embryologist
Academish Ziekenhuis Laarbeeklaan, Belgium

Professor Alan Handyside
Professor
Leeds Hospital

Dr Joyce Harper
Lecturer in Human Genetics and Embryology
University College London Hospitals

Dr Sue Pickering
Scientific Director
Guy's and St Thomas' Hospitals Trust, London

Professor Andre Van Steirteghem
Scientific Co-ordinator
Academish Ziekenhuis Laarbeeklaan, Belgium

Social and ethical

Mrs Linda Breeze
Psychosexual Therapist and Fertility Counsellor
Royal Devon and Exeter Hospital

Mrs Jennifer Clifford
GP Counsellor
Self Employed

Mrs Elizabeth Corrigan
Business Manager and Nursing Director
Centre for Reproductive Medicine, Bristol

Ms Marilyn Crawshaw
Teaching Fellow in Social Work
University of York

Mrs Jennifer Dunlop
Senior Counsellor
Central Manchester Healthcare Trust (NHS)

Mrs Heideh Hillier
IVF Nurse Manager
Edinburgh Assisted Conception Unit

Ms Jennifer Hunt
Senior Infertility Counsellor
Hammersmith Hospital, London

Ms Margret Inglis
Counsellor
Royal Free Hospital, London

Mrs Helen Kendrew
Clinical Nurse Manager
Bath Assisted Conception Clinic

Ms Janice Kerr
Manager of Cancer Service
National Service Framework
Worchester Acute NHS Trust

Mrs Caroline Lewis
Assisted Conception Unit Manager
Woking Nuffield Hospital ACS Unit

Ms Katherine Mangold
Clinical Manager
BMI Portland Hospital for Women and Children
London

Dr Jim Monach
Lecturer
School of Health and Related Research,
University of Sheffield

Mrs Yvonne Payne
Assisted Conception Services Manager
Thames Valley Nuffield Hospital

Ms Marney Prouse
Vice President
Guy Carpenter and Co (Ltd)

Mrs Roz Shaw-Smith
Counselling Psychologist
John Radcliffe Hospital, Oxford

Ms Jennifer Speirs
Freelance Infertility Counsellor and Social Work
Consultant
Edinburgh

Appendix Four

Ongoing research projects licensed by the HFEA
(as of 31 August 2003)

In vitro development and implantation of normal human preimplantation embryos and comparison with uni- or poly-pronucleate pre-embryos
University of Manchester
Research started: 1 March 1997
Number of HFEA licences issued: 4*

To measure the activity of metabolic enzymes in spare human preimplantation embryos
The Hammersmith Hospital, London
Research started: 30 July 1993
Number of HFEA licences issued: 8

To measure the activity of enzymes implicated in genetic disorders
The Hammersmith Hospital, London
Research started: 30 July 1997
Number of HFEA licences issued: 8

Preimplantation genetic diagnosis - parallel investigations
The Hammersmith Hospital, London
Research started: 30 July 1997
Number of HFEA licences issued: 8

Biochemistry of early human embryos
University of York
Research started: 25 January 1995
Number of HFEA licences issued: 5

Improving methods for biopsy and preimplantation diagnosis of inherited genetic disease of human preimplantation embryos
Guys Hospital, London
Research started: 15 July 1994
Number of HFEA licences issued: 8

A study of the effects of cell death on the further development of human embryos *in vitro*
Centre for Reproductive Medicine, Coventry
Research started: 25 February 1996
Number of HFEA licences issued: 4

Maturation of fertilisation of human eggs *in vitro*
Clarendon Wing, Leeds
Research started: 14 March 1997
Number of HFEA licences issued: 2

Segregation of mitochondrial DNA in human embryos
Centre for Reproductive Medicine, Coventry
Research started: 1 June 1998
Number of HFEA licences issued: 2*

Detection of autosome and sex chromosome abnormalities in human preimplantation embryos using FISH and the polymerase chain reaction
Glasgow Royal Infirmary
Research started: 2 March 1998
Number of HFEA licences issued: 3

In vitro maturation and fertilisation of immature oocytes from women undergoing ICSI treatment
Centre for Reproductive Medicine, Coventry
Research started: 11 May 1998
Number of HFEA licences issued: 3

Development of a model to study implantation in the human
Oxford Fertility Unit
Research started: 9 March 1998
Number of HFEA licences issued: 3

The development of novel preimplantation genetic diagnosis (PGD) procedures and the study of early human development
University College Hospital, London
Research started: 22 June 1998
Number of HFEA licences issued: 3

Investigation of embryonic-endometrial dialogue during the peri-implantation period *in vitro*
Section of Reproductive and Developmental Medicine, Sheffield Teaching Hospitals
Research started: 1 September 1998
Number of HFEA licences issued: 3*

Metabolism of human embryos as an index of quality
University of Aberdeen
Research started: 22 June 1999
Number of HFEA research licences issued: 4

Biopsy of prenucleate embryos
Liverpool Women's Hospital
Research started: 14 February 2000
Number of HFEA licences issued: 3

An investigation of the effect of blastomere removal for preimplantation genetic diagnosis on subsequent embryonic development
Newcastle Fertility Centre at Life
Research started: 21 June 2000
Number of HFEA research licences issued: 2

In vitro maturation and cryopreservation of human oocytes
NURTURE, Nottingham
Research started: 18 July 2000
Number of HFEA research licences issued: 2

Isolation and characterisation of cell lines from human preimplantation embryos. Study of the involvement of the cellular stress response in the cause of embryo attrition and developmental defects in the human using embryonic stem cells
Newcastle Fertility Centre at Life
Research started: 1 September 2000
Number of HFEA research licences issued: 3

Derivation of pluripotent human embryo cell lines
Institute for Stem Cell Research, University of Edinburgh
Research started: 4 November 2002
Number of HFEA research licences issued: 1

Correlation of embryo morphology with ability to generate embryonic stem cell lines and subsequent growth differentiative characteristics
Guys Hospital, London
Research started: 15 April 2002
Number of HFEA research licences issued: 1

A novel protocol for extracting cells during embryo biopsy without the use of acid tyrodes
CARE at the Park Hospital, Nottingham
Research started: 17 September 2002
Number of HFEA research licences issued: 1

Platform technologies underpinning human embryonic stem cell derivation
Roslin Institute research, Scotland
Research started: 1 July 2003
Number of HFEA research licences issued: 1

Functional genomics of pluripotent stem cells and their progeny
London Fertility Centre
Research started: 1 November 2002
Number of HFEA research licences issued: 1

Epigenetic studies of preimplantation embryos and derived human embryonic stem cells
Newcastle Fertility Centre at Life Research started: 5 August 2003 Number of HFEA research licences issued: 2

To derive human embryonic stem cells and trophoblast cell lines
Oxford Fertility Unit
Research started: 14 August 2003
Number of HFEA research licences issued: 1

* research based at more than one centre

Appendix Five

HFEA peer reviewers (as of 31 August 2003)

Professor Jonathan Aitken
Professor, Medical Research Council, Reproductive Biology Unit, Edinburgh

Mr Adam Balen
Person Responsible and Accredited Consultant,
Leeds General Infirmary, Leeds

Dr Siladitya Battacharya
Accredited Consultant, University of Aberdeen

Dr Virginia Bolton
Senior Lecturer and Senior Embryologist,
King's College Hospital, London

Professor Nigel A Brown
Professor of Developmental Biology,
St George's Medical School, London

Professor Keith Campbell
Professor of Animal Development, University of Nottingham

Dr John Carroll
Lecturer in field of Physiology and Developmental Biology,
University College London

Dr J R T Coutts
Retired Reader in Reproductive Endocrinology, Glasgow

Professor Mark Curry
Senior Lecturer, De Montford University, Lincolnshire

Ms Karin Dawson
Consultant Embryologist, Hammersmith Hospital, London

Dr Simon Fishel
Managing Director, Centres for Assisted Reproduction (CARE) Ltd Park Hospital, Arnold, Nottingham

Dr Richard Fleming
Biochemist, Glasgow Royal Infirmary

Professor Tom Fleming
Professor and Lecturer, Cell Science Division,
School of Biological Sciences, University of Southampton

Professor Stephen Franks
Professor of Reproductive Endocrinology,
St Mary's Imperial College School of Medicine Campus, London

Professor Lynn Fraser
Professor of Reproductive Biology, King's College, London

Dr Rafet Gazvani
Consulting Gynaecologist and Sub-Specialist in New Production Medicine, The Women's Hospital, Liverpool

Dr Mark Hamilton
Consultant Obstetrician and Gynaecologist and Clinical Senior Lecturer, University Of Aberdeen

Professor Alan Handyside
Professor, Leeds Hospital

Dr Joyce Harper
Lecturer in Human Genetics and Embryology,
University College London Hospitals

Dr Geraldine Hartshorne
Scientific Director, Walsgrave Hospital NHS Trust, Coventry

Dr Stewart Irvine
Consultant/Clinical Scientist, Medical Research Council,
Human Reproductive Sciences Unit, Edinburgh

Dr Mark Johnson
Consultant Obstetrician, Chelsea and Westminster NHS Trust,
London

Professor Martin Johnson
Professor of Reproductive Sciences and Fellow of
Christ Dr Sue Kimber, Reader in Biological Sciences,
School of Biological Sciences, Manchester

Mr Charles Kingsland
Consultant Obstetrician and Gynaecologist and Honorary
Lecturer, The Women's Hospital, Liverpool

Professor G. E. Lamming
Retired/Emeritus Professor, University of Nottingham

Dr Alan McDermott
Director, Regional Cytogenetics Centre, Southmead Hospital,
Bristol

Dr Alan McNeilly
Professor and Deputy Director,
Medical Research Council Human Reproductive Sciences Unit,
Edinburgh

Dr Tony Michael
Senior Lecturer in Biochemistry and Molecular Biology,
University College London

Professor Marilyn Monk
Head of Molecular Embryology Unit,
Institute of Child Health, London

Professor Harry D. Moore
Professor of Reproductive Biology, Section of Reproductive and
Developmental Medicine, Jessop Wing, Hallamshire Hospital,
Sheffield

Professor Robert Moore
Officially Retired, Molecular Embryologist, Agricultural & Food
Research Council (AFRC) Institute of Animal Physiology,
Cambridge

Dr David Pegg
Director, Medical Cryobiology Unit, Biology Department,
University of York

Dr Helen Picton
Senior Lecturer in Reproductive Biology and Scientific Director of
Assisted Conception Unit, Leeds Teaching Hospitals NHS Trust

Dr Ian Sargent
University Reader, University of Oxford

Professor Austin Smith
Head of Institute, Institute for Stem Cell Research,
University of Edinburgh

Dr Karl Swann
Reader in Cell Physiology, University College London

Professor Allan Templeton
Professor of Obstetrics and Gynaecology,
University of Aberdeen

Professor Robert Webb
Head of Animal Sciences, University of Nottingham

Dr Michael Whitaker
Dean of Research, University of Newcastle
Professor David Whittingham, Biology Professor,
Department of Anatomy and Developmental Biology,
St Georges Hospital Medical School, London

Dr Maureen Wood
Scientist, University Of Aberdeen

Appendix Six

HFEA Members' interests (as of 31 August 2003)

The HFEA maintains a register of Members' interests and has in place procedures to ensure that Members do not participate in decisions where there is a potential conflict of interests. The register of interests is available to the public via the HFEA website. Listed below are the employment and public appointment details of all HFEA Members.

Suzi Leather (Chair)

Personal interests

Consultancies and/or direct employment:
- None

Fee-paid work other than that associated with HFEA Authority:
- None

Other Public Appointments:
- Member of the Medical Research Council's UK Stem Cell Bank Steering Committee
- Member of the Human Genetics Commission

Other:
- Member of the Labour Party
- Member of the Christian Socialist Movement
- Individual member of the National Heart Forum
- Member of the Child Poverty Action Group
- Trustee of the Food Foundation
- Member of the Organophosphate Information Network
- Advisor to the Maternity Alliance
- Member of Chancellor's Advisory Council, University of Exeter

Professor Tom Baldwin

Personal interests

Consultancies and/or direct employment:
- Professor of Philosophy at the University of York

Fee-paid work other than that associated with HFEA Authority:
- None

Other Public Appointments:
- Member of Stem Cell Steering Committee

Other:
- Member of the Nuffield Council on Bioethics

Professor David Barlow

Personal interests

Consultancies and/or direct employment:
- Nuffield Professor of Obstetrics and Gynaecology, University of Oxford
- Head of Oxford Fertility Unit and HFEA Person Responsible

Fee-paid work other than that associated with HFEA Authority:
- Novo Nordisk (occasional consultancy without retainer)

Other Public Appointments:
- NICE Fertility Guidelines Development Group (Chairman)

Other:
- Directorships:
  - British Menopause Society Publications Limited
  - British Menopause Society
  - Oxford Reproductive Biosystems (not trading)
- Memberships:
  - Academy of Medical Sciences (Fellow)
  - National Osteoporosis Society (Chairman)
  - British Menopause Society (Past chairman)
  - Royal College of Obstetricians and Gynaecologists (Fellow)
  - American Society for Reproductive Medicine
  - British Fertility Society
  - European Society for Human Reproduction and Embryology
  - International Menopause Society
  - NICE Osteoporosis Guidelines Development Group (Chairman
- Trusteeships:
  - National Osteoporosis Society
  - British Menopause Society
  - Oxford Hospitals Charitable Trust Funds
- Advisory Committees:
  - Astra Zeneca
  - Eli Lilly
  - Medical Research Council
  - Merck
  - Pharmacia
  - Servier
  - Takeda

Professor Christopher Barratt

Personal interests

Consultancies and/or direct employment:
- Scientific Director of the Birmingham Women's Health Care
- Occasional consultancy in legal cases relating to assisted conception and male factor infertility

Fee-paid work other than that associated with HFEA Authority
- None

Other Public Appointments:
- None

Professor Peter Braude

Personal interests

Consultancies and/or direct employment:
- Head of Department of Women's Health, Guys, Kings and St Thomas' School of Medicine
- Director of the Centre for Preimplantation Genetic Diagnosis, Guy's and St Thomas' Trust
- Honorary consultant in Gynaecology, Guy's and St Thomas' Trust
- Occasional Consultancy and expert advisor to:
  - Serono Pharmaceuticals
  - Ares Serono
  - Tommy's the Baby Charity
  - Wellbeing
  - PPP
  - Progress
  - Bertarelli Foundation

Other Public Appointments:
- None

Memberships:
- Royal College of Obstetricians and Gynaecologists
- British Fertility Society
- American Society for Reproductive Medicine
- European Society for Human Reproduction and Embryology
- The Galton Society
- Association of Professors of Obstetrics and Gynaecology

Ivor Brecker

Personal interests

Consultancies and/or direct employment:
- General Dental Practitioner, Retired
- Medico-legal consultancy for Community Health Councils (voluntary)
- Consultancies for Dentists and Solicitors

Fee-paid work other than that associated with HFEA Authority:
- None

Other Public Appointments:
- None

Clare Brown
Personal interests
Consultancies and/or direct employment:
- Executive Director of CHILD, the National Infertility Support Network

Fee-paid work other than that associated with HFEA Authority:
- None

Other Public Appointments:
- Member of the National Institute of Clinical Excellence (NICE) Fertility Guideline Development Group

Other:
- Patient representative on the British Fertility Society Management Committee
- President of the International Federation of Infertility Patient Associations
- Member of the European Society of Human Reproduction and Embryology
- Member of the Labour Party
- Chair of the National Infertility Awareness Campaign
- Chair of the Organising Committee of National Infertility Day

Professor Iain Cameron
Personal interests
Consultancies and/or direct employment:
- Professor of Obstetrics and Gynaecology at the University of Southampton
- Past consultancy with Leiras, Schering and Takeda (Pharmaceutical)

Fee-paid work other than that associated with HFEA Authority:
- Publishing / Lecturing for various organisations

Other Public Appointments:
- None

Other:
- Royal College of Obstetricians and Gynaecologists (Chairman joint RCOG / WellBeing Research Advisory Committee)
- NICE (Specialist Adviser (Menorrhagia))
- MRC Advisory Board
- Scientific Committee, National Endometriosis Society
- Pharmaceuticals Panel, Health Technology Assessment Programme, NHS Executive
- Memberships:
  - Society for Reproduction and Fertility
  - Blair Bell Research Society
  - British Fertility Society
  - American Society for Reproductive Medicine
  - Endocrine Society
  - Society for the Study of Reproduction
  - Society for Gynecologic Investigation
  - Society for Endocrinology

Jane Denton
Personal interests
Consultancies and/or direct employment:
- Director of the Multiple Births Foundation, Queen Charlotte's and Chelsea Hospital London

Fee-paid work other than that associated with HFEA Authority:
- None

Other Public Appointments:
- None

Other:
- Human Fertility (Editorial Board Member)
- Memberships
  - Royal College of Nursing – Fertility Nurses Group
  - Ethics Advisory Panel, Royal College of Nursing
  - British Infertility Counselling Association
  - International Society for Twin Studies

Professor Andrew Grubb
Personal interests
Consultancies and/or direct employment:
- Professor of Medical Law and Head of Law School at University of Cardiff

Fee-paid work other than that associated with HFEA Authority:
- Barrister

Other Public Appointments:
- Part time Immigration Adjudicator, Immigration Appellate Authority
- Member, Royal College of Physicians Committee on Ethical Issues in Medicine
- Member, Medical Research Council/Department of Health Research Advisory Group for Transmissible Spongiform Encephalopathies (TES)
- Fellow, Academy of Medical Sciences
- Vice President, Welsh Medico-Legal Society

Professor Neva Haites
Personal interests
Consultancies and/or direct employment:
- Professor at University of Aberdeen
- Honorary Consultant in Clinical Genetics at Grampian University Hospitals Trust
- Board Member – NHS Grampian
- Associate Dean (Clinical) – University of Aberdeen

Fee-paid work other than that associated with HFEA Authority:
- Member of Government Advisory Committee – Committee on Medical Aspects of Radiation in the Environment (COMARE)
- Examining Post-Graduate Degrees

Other Public Appointments:
- Member of National Screening Committee
- Member of the Scottish Cancer Group

Other
- Member of Academy Medical Science (Fellow)
- Member of Royal College of Pathology (Fellow)
- Member of Royal College of Physicians (Fellow)
- Member of American Society of Human genetics
- Member of British Society of Human Genetics
- Member of European Society of Human Genetics
- Member of the Pregnancy and New Born Screening Implementation Group
- Chair Scottish pregnancy Screening Group

Emily Jackson
Personal interests
Consultancies and/or direct employment:
- Senior Lecturer in Law, London School of Economics

Fee-paid work other than that associated with HFEA Authority:
None
Other Public Appointments:
None

[illegible] Jamieson
Personal interests
Consultancies and/or direct employment:
Consultant Embryologist; Assisted Conception Service, Glasgow Royal Infirmary
Fee-paid work other than that associated with HFEA Authority:
None
Other Public Appointments:
None
Other:
- Member of the Association of Clinical Embryologists (Treasurer, Executive Committee and Professional Development Committee)
Department Of Health Assessor For Clinical Embryology
- Embryology Assessor for the Health Professions Council
- Member of the European Society for Human Reproduction and Embryology
- Member of the British Fertility Society
- Member of the Society for Reproduction and Fertility

Simon Jenkins
Personal interests
Consultancies and/or direct employment:
- Columnist – The Times

Fee-paid work other than that associated with HFEA Authority:
- None

Other Public Appointments:
- None

Other:
- None

[illegible]alter Merricks
Personal interests
Consultancies and/or direct employment:
- Chief Ombudsman, Financial Ombudsman Service

Fee-paid work other than that associated with HFEA Authority:
None
Other Public Appointments:
None
Other:
Secretary and treasurer of Donor Conception Network, a charitable network of parents with children conceived with donated gametes – donor insemination and IVF with donor sperm or eggs – adult offspring and those contemplating or undergoing treatment

[illegible] Nathan
Personal interests
Consultancies and/or direct employment:
- Freelance broadcaster and producer

Fee-paid work other than that associated with HFEA Authority:
- Lay Member, Professional Conduct Committee of the Bar Council
- Chair, Lambeth's Children First Commission

Other Public Appointments:
- Member of Radio Authority
- Member of the Criminal Injuries Compensation Appeals Panel
- Member, Regulatory Decisions Committee, Financial Services Authority
- Marshall Commissioner
- Member, Ofcom and Deputy Chairman of Ofcom's Content Board
- Member, ICSTIS

Other:
- Council Member, Jewish Museum

The Right Reverend Dr Michael James Nazir-Ali
Personal interests
Consultancies and/or direct employment:
- Lord Bishop of Rochester
- Director, Rochester Diocesan Board of Finance
- President, Rochester Diocesan Board of Education

Fee-paid work other than that associated with HFEA Authority:
- None

Other Public Appointments:
- Member of House of Lords

Other:
- Company Director, Central Board of Finance of the Church of England
- Chairman of Council at Trinity College, Bristol
- Visiting Professor, Faculty of Humanities, University of Greenwich
- Fellow, St. Edmund Hall, Oxford University

Sharmila Nebhrajani
Personal interests
Consultancies and/or direct employment:
- Chief Operating Officer and Finance Director, BBC New Media and Technology

Fee-paid work other than that associated with HFEA Authority:
- None

Other Public Appointments:
- Associate Advisor, Prime Minister's Delivery Unit

Appendix Seven

Performance indicators (for the period April 2002-March 2003 unless otherwise indicated)

Inspection and licensing

There has been an improvement in the performance of the inspection and licensing functions as the indicators below demonstrate when compared to previous years, this is especially in relation to research licences and variation of treatment licences. One area where performance suffered during the year was in treatment licence renewals. This was due to a severe shortage of regulation staff in the early part of the year which led to delays in inspection and hence in renewals going to Licence Committees. This has now been rectified through the recruitment of additional staff and this has already led to demonstrably better performance than shown in the figures below. The HFEA is also reviewing the licensing process with the intention of improving performance still further.

Number of licence applications put before HFEA Licence Committees within three months of receipt of completed applications.

New Treatment Licences

Received	Number considered within timescale
3	3

Renewal Licences

Received	Number considered within timescale
60	26

Research – New Applications

Received	Number considered within timescale
9	7

Research – Renewal Applications

Received	Number considered within timescale
5	3

Number of Variations Granted

Received	Number considered within timescale
109	84

Reports resulting from inspections available to centre within four weeks = 60%

New licence applications processed within four months from receipt = 100%

Number of inspections booked more than two months in advance = 50%

Number of research licences approved = 4

6 monthly incidents for the period April 2002 – September 2002

Active incidents at start of period	25
Active incidents at end of period	40
Incidents reported	39
Incidents resolved	24

6 monthly incidents for the period October 2002 – March 2003

Active incidents at start of period	40
Active incidents at end of period	16
Incidents reported	26
Incidents resolved	50

These statistics also include patient complaints. In November 2002, the HFEA introduced a separate process to deal with patient complaints.

Annual inspection cancellation figures

Annual Inspections

as planned	91	(73%)
cancelled but rescheduled	30	(24%)
cancelled and not rescheduled	0	(0%)
exempted by Licence Committee	3	(2%)

Financial

Payments
Target: 95% of undisputed invoices to be paid in 30 days

Out-turn: 90% paid in 30 days.

Debts
Target: 95% collected in 60 days

Out-turn: 74%. Affected by difficulties with the old (now replaced) billing procedures.

Unqualified Audit Report
Achieved

Monthly billing of clinics achieved in 3 weeks
Monthly billing within 3 weeks of the month end during which clinics submitted their returns of treatments was achieved from July 2002 onwards.

Corporate

Number of hits on the HFEA Website = 3,070,815
August 2002 – August 2003

Number of events organised by the HFEA = 7
(Code of Practice Seminar, HFEA Annual Conference, Sex Selection Parliamentary Meeting, Fees consultation Stakeholder Meetings x3, Definition of a Treatment Cycle Seminar)

Number of patient/public enquiries handled between September 2002 – July 2003 = 8,022

Financial Accounts

Financial Accounts for the Year Ended 31 March

Background

The Human Fertilisation and Embryology Authority (HFEA) formally came into being on 7th November 1990 and began operating on 1st August 1991. The HFEA was created by the Human Fertilisation and Embryology Act 1990 to license and regulate human embryo research and specified forms of infertility treatment. The HFEA is an executive Non-Departmental Public Body sponsored by the Department of Health.

Statutory Remit

One of the main statutory functions of the HFEA is to regulate, by means of a licensing system, centres undertaking infertility treatments involving the creation or use of human embryos outside the body, the storage or donation of embryos or gametes or research involving human embryos.

The HFEA is also required to maintain a register of information about all licensed treatments performed in the United Kingdom. This contains information about those receiving treatment, donors of gametes and embryos and any children born as a result of such treatments. Anyone born as a result of treatment since 1991 and who has reached the age of 18 may approach the HFEA for information to confirm whether or not they were born as a result of treatment services and, if so whether this treatment involved the use of donated gametes. A person aged 16 or over who is intending to marry can request information to determine whether or not they are related to a prospective spouse.

In addition, the HFEA has other statutory responsibilities including:

- publicising the services provided by it and by the centres it licenses;
  publishing a Code of Practice giving guidance to centres on how they should carry out licensed activities;
  giving information and advice to donors, to people seeking treatment or storage, or to people considering such action; and
  keeping the field under review and providing advice to the Secretary of State for Health, if so requested.

Principal activities

The year 2002/03 saw major developments in the work of the HFEA, with significant improvements in a number of key areas.

Regulation

The HFEA's primary objective remains the licensing and inspection of clinics and centres carrying out *in vitro* fertilisation donor insemination and human embryo research. This includes regulation of the storage of gametes and embryos. A major programme of investment in, and modernisation of, regulation began in 2002/03. This included:-

- an increase in the number and skills-base of regulation and inspection staff;
- development of new inspection protocols and processes;
- introduction of a more rigorous clinic audit programme.

During 2002/03, there were 273 HFEA visits to licensed centres comprising:

- 121 annual inspection visits
- 93 audit visits
- 24 visits for incident management
- 8 variation inspections
- 6 advisory visits
- 18 practitioner inspections (embryo biopsy/Intra-Cytoplasmic Sperm Injection-ICSI)
- 3 visits to new centres

During 2002/03, 257 items of business were considered at 36 Licence Committee meetings; of these were:

- 34 interim licences
- 69 variations to licences
- 30 short licences
- 25 applications for recognition of specific practitioners
- 7 initial licences
- 3 revocations of licence
- 60 renewals
- 29 miscellaneous

Established centres are subject to a three year licensing cycle composed of one full and two interim inspections.

Information Management

The HFEA collects data from all licensed centres about IVF and donor insemination treatments, their outcomes and about ever donor. A major redesign of the HFEA's Data Register began in 2002/03, to ensure the organisation can fulfil its statutory obligation to provide information to offspring, including the development of a new interim data register. The HFEA published Patients' Guides giving the outcome data for individual clinics. This information is also published on the HFEA's website **(www.hfea.gov.uk).**

Communications

The HFEA improved its communications capacity to enable it to respond to the increased demands from the media and from th wider public. Two major public consultations were carried out, or the level of fees and on sex selection.

Policy
New policies and guidance on Preimplantation Genetic Diagnosis (PGD) and Preimplantation Genetic Screening (PGS) were produced.

Finance and Corporate Development
A new fees strategy was developed and implemented. A new business framework and a risk management strategy were put in place to ensure stronger internal governance.

HFEA Clinic Audits
Further to the qualification of the previous year's accounts by the Comptroller & Auditor General (C&AG), a detailed and intensive audit of clinics was undertaken during 2002/03 by a specialist HFEA audit team. The findings of this audit demonstrated clearly that:

- there was no significant under-reporting of treatment activity by licensed clinics;
- there was no material variance between the value of fees billed by the HFEA and the clinics' declared activity.

Accordingly, the qualification included in the C&AG's audit report for Financial Year 2001/02 has been removed from this year's audit report.

The HFEA audit team also looked at the accuracy of reporting of treatment cycles in the period 1991-2002. Again the findings indicated that, historically, there was no evidence of material error in reporting by clinics, nor of under-billing by the HFEA. The in-depth audit will continue in 2003/04, but will be developed as a more integral element in the wider inspection process.

Financial Results for 2002/03 and Going Concern
HFEA made a deficit of £305,968 during the year. This incorporates an exceptional item, being the increase in provision for future pension liabilities relating to the transfer of the HFEA's by-analogy pension scheme into membership of the Principal Civil Service Pension Scheme (PCSPS).

The total future pension liability at 31 March 2003 has been calculated by the Government Actuary's Department in the sum of £1.22m. The net increase in provision needed to reflect this liability in the Income & Expenditure Account for the year ended 31st March 2003 amounted to £288,330.

The Department of Health undertook to fund the full liability of £1.22m and this was incorporated in their approved expenditure estimates. This money was received by HFEA on 27 June 2003, and payment in full settlement of the liability was made on 30th June 2003 to the Civil Superannuation Vote.

The National Audit Office (NAO) have required us to follow the accounting treatment for this item contained in Treasury guidance, as jointly determined between NAO and Treasury. Although the full future pension liability has been included in the Accounts, no provision has been made for the funding subsequently received from the Department of Health which has now settled the amount due. Therefore the balance sheet of the HFEA at 31st March 2003 is shown in deficit by £541,261. Had this funding from the Department of Health been included, there would have been a surplus for the year of £914,047, and the balance sheet would have shown total net assets and reserves of £678,754.

The explanation provided by the Treasury and NAO for this treatment, and for not recognising a post balance sheet adjusting event under UK GAAP, is that under the normal conventions applying to parliamentary control over income and expenditure, such grants must be accounted for on a cash basis. Therefore this funding could not be recognised until received.

On the basis that the necessary funding for this pension liability has now been received and full settlement made, it has accordingly been considered appropriate to adopt a going concern basis for the preparation of these financial statements.

Disabled Employees
The policy of HFEA is to make all reasonable adjustments to the working environment when required to meet the needs of disabled employees.

Equal Opportunities
The HFEA is an equal opportunities employer with a policy of providing equality of opportunity for all staff members and job applicants. The HFEA does not discriminate against anyone on the ground of age, race, colour, ethnic or national origin, gender, marital status, responsibility for children or dependents, disability, sexual orientation or religious or political beliefs.

Consultation with Employees
The HFEA's policy is to involve staff and to consult them on relevant matters such as health, safety and welfare. Issues that may be of interest or concern are discussed at regular staff meetings. An appraisal system has been enforced throughout the year to improve performance review and the development of staff.

Payment of Suppliers
The HFEA has adopted the principles of the 'Better Payment Practice Code' and works to ensure that all undisputed invoices are paid within 30 days. In 2002/03 the HFEA paid 90% of invoices within 30 days (2001/02 98%) and 99% were paid within 60 days (2001/02 100%).

Future Developments
During 2003/04 the HFEA will work towards the following objectives:-

- to achieve a stronger more effective and consistent process of regulating fertility services and storage of gametes and embryos;
- to achieve a more comprehensive open and systematic approach to licensing and regulating research;
- to put in place a robust information management strategy and framework;

to improve the range, quality and speed of communication and information for all stakeholders including patients, public and the Authority;
to develop and implement clear policies based on evidence and ethical considerations, supporting best clinical practice underpinning regulation, and contributing to the ongoing improvement in standards;
to work in an open and honest way within the boundaries of the codes of confidentiality;
to provide valid and comprehensive information for patients and the public;
- to ensure through the establishment of clear systems that the Authority meets its statutory, financial, and corporate responsibilities demonstrating efficiency, effectiveness and value for money;
- to develop and implement a human resource strategy that values staff and ensures that appropriate capacity and skills are developed;
- to strengthen partnership working with other statutory and voluntary organisations including patient groups.

Ms Angela McNab
Interim Chief Executive
10th July 2003

Annex A

Authority Members
Membership of the Human Fertilisation and Embryology Authority during the year 2002/03 was as follows:-

Suzi Leather (Chair)
Lady Julia Tugendhat (Deputy Chair - retired 6/11/02)
Professor Thomas Baldwin
(Deputy Chair with effect from 7/11/02)
Mrs Jane Denton (Director of Sub-committees)
Dr Sue Avery (retired 6/11/02)
Professor David Barlow
Professor Christopher Barratt
Professor Peter Braude
Mr Ivor Brecker
Ms Clare Brown (appointed 2/12/02)
Professor Iain Cameron
Professor Christine Gosden (retired 6/11/02)
Professor Andrew Grubb
Professor Neva Haites (appointed 2/12/02)
Dr Maybeth Jamieson (appointed 2/12/02)
Mr Simon Jenkins
Professor Henry Leese (resigned 23/9/02)
Professor Stuart Lewis (retired 6/11/02)
Mr Walter Merricks (appointed 02/12/02)
Ms Sara Nathan
Rt. Revd. Dr Michael Nazir-Ali
Ms Sharmila Nebhrajani
Dr Francoise Shenfield (retired 6/11/02)
Mrs Jean Smith (retired 6/11/02)
Mrs Liz Woods (retired 6/11/02)

Statement of the Authority's and Chief Executive's Responsibilities

Authority Members' Responsibilities
Under section 6(1) of the Human Fertilisation and Embryology Act 1990, the Human Fertilisation and Embryology Authority is required to prepare a statement of accounts for each financial year in the form and on the basis determined by the Secretary of State, with the consent of the Treasury. The accounts are prepared on the accruals basis, and must show a true and fair view of the Authority's state of affairs at the year-end and of its income and expenditure, total recognised gains and losses, and cash flow for the financial year.

In preparing the accounts the Authority is required to:-
- observe the Accounts Directions issued by the Secretary of State, including the relevant accounting and disclosure requirements, and apply suitable accounting policies on a consistent basis;
- make judgements and estimates on a reasonable basis;
- state whether applicable accounting standards have been followed, and disclose and explain any material departures in the financial statements;
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Authority will continue in operation.

Accounting Officer's Responsibilities
The Accounting Officer of the Department of Health has designated the Chief Executive of the Human Fertilisation and Embryology Authority as the Accounting Officer for the Authority. Her relevant responsibilities as Accounting Officer, including her responsibility for the propriety and regularity of the public finances for which she is answerable and for the keeping of proper records, are set out in the Non Departmental Public Bodies' Accounting Officer Memorandum.

Statement on Internal Control

Scope of Responsibility

As Accounting Officer, I have responsibility for maintaining a sound system of internal control that supports the achievement of the HFEA's policies, aims and objectives as set out in the Human Fertilisation and Embryology Act 1990, the Authority's Business Plan, and by Ministers within the Department of Health (DH), whilst safeguarding the public funds and departmental assets for which I am personally responsible, in accordance with the responsibilities assigned to me in DH correspondence.

The Management Statement, agreed between the Department of Health and the HFEA, sets out the accountability framework within which the Authority's work will be monitored. It was revised in 2002/03, and was formally approved by the Authority on 16th January 2003. This requires:-

- prior approval by the Department of the HFEA's annual Business Plan, including an assessment of risks to the organisation;
- submission to the Department of regular monitoring information on progress in implementing the Plan;
- an annual accountability meeting between DH Ministers and the Chair and Chief Executive of the HFEA.

In addition, DH representatives customarily attend Authority meetings, and meetings of key standing committees (Organisation and Finance, Audit, and Information Management Programming Board). 2002/03 has been a year of significant change within the HFEA, and during this period liaison with DH has been very close. In addition to the formal accountability framework, there have been monthly meetings between the Department's Sponsoring Division and the Authority's Senior Management Team (SMT).

2. The Purpose of the System of Internal Control

The system of internal control is designed to manage risk to a reasonable level rather than to eliminate all risk of failure to achieve policies, aims and objectives. It can therefore only provide reasonable and not absolute assurance of effectiveness.

In the Statement of Internal Control signed by my predecessor on 15th July 2002, a commitment was given to carry out the following:-

- appoint a local risk champion;
- identify departmental 'operational risk champions';
- arrange a regular programme of facilitated workshops to identify and keep up to date the record of risks facing the organisation;
- develop and maintain an organisation-wide risk register;
- design a Risk Management Strategy by March 2003 that looks forward to 2007.

This programme of work was completed with a risk management strategy and a risk register being agreed by the Authority at its meeting on 20th March 2003. This has put in place a process which enables the HFEA to identify and prioritise the risks to the achievement of its policies, aims and objectives, to evaluate the likelihood of those risks being realised and the impact should they be realised, and to manage them efficiently, effectively and economically. This process of internal control accords with Treasury guidance.

3. Capacity to Handle Risk

The Authority is very aware that we are operating in a high risk area, and of the importance that risks are managed appropriately. The Chair, key committee chairs and the SMT, were involved in developing the risk strategy and risk register. It is also recognised that effective risk management must be resourced, and this has been a factor in the development of the organisation and staffing levels. The recruitment of the SMT is now complete, and there has been significant expansion of skilled staff in key areas, such as Regulation, IT, and Communications. Risk management is now led by a member of the SMT - the Director of Resources and Corporate Development - and an Assistant Director has specific responsibility for supporting the development of risk management across the organisation. Staff training is a central element in the programme now under way to implement the risk strategy agreed by the Authority in March.

4. The Risk and Control Framework

The HFEA aims to operate with a well-balanced regard for risk. The risk strategy defines risk as the failure to perform our statutory functions, and inability to achieve the Business Plan objectives, whether through negative action, or inaction. This could also include the failure to identify and exploit new opportunities. The risk register was built up through focussed discussions and workshops with staff in all departments and levels. It identifies the probability and impact of each risk, and the related controls to manage the risk. As part of the new strategy, a Risk Management Group has been established, involving all departments which will monitor that actions to control risk are being implemented, and the Register updated as required.

The process of developing the risk register highlighted the reputational risk of the HFEA not fulfilling its statutory obligations, particularly failing to regulate infertility treatment, and embryo research. Although a formal risk strategy was not agreed until 20th March 2003, the need for change in the HFEA was identified through a number of reviews referred to in the last Statement on Internal Control. Significant changes in regulation, information management, communications and corporate governance were put in place during 2002/03. Also there is a growing awareness of risk at all levels of the organisation. Regulatory staff receive risk assessment training, a Risk Matrix is being developed to inform the clinic inspection process, and all new project proposals include an assessment of risk.

Other key developments during the year include:

HFEA Clinic Audits

As noted in the Foreword to these Accounts, further to the qualification of the previous year's accounts by the Comptroller & Auditor General, a detailed and intensive audit of clinics was undertaken during 2002/03 by a specialist HFEA audit team. The findings of this audit demonstrated clearly that:

- there was no significant under-reporting of treatment activity by licensed clinics;
- there was no material variance between the value of fees billed by the HFEA and the clinics' declared activity.

The HFEA audit team also looked at the accuracy of reporting of treatment cycles in the period 1991-2002. Again the findings indicated that, historically, there was no evidence of material error in reporting by clinics, nor of under-billing by the HFEA. The in-depth audit will continue in 2003/04, but will be developed as a more integral element in the wider inspection process.

Corporate Governance

Following a number of internal and external reviews, the HFEA corporate governance structure was completely overhauled. New governance instruments (Management Statement, Standing Orders, Standing Financial Instructions) are now in place. The committee structure was reviewed to reflect current best practice. This included reducing the number of committees, revising the appointments process and terms of reference. There were also changes in the role of Authority Members, notably they are no longer involved in the inspection process.

Information Management

Significant progress was made during the year on the development of the HFEA's information systems, to enable the Authority to fulfil its statutory obligations. A new data register was established, offering more comprehensive and user-friendly records. The new systems are more robust, and have been subject to rigorous testing prior to use. During the coming year, information from the old registers will be validated and transferred onto the new system. This process is being managed within a PRINCE framework, and overseen by a high-level Information Management Programming Board, chaired by myself, and involving Members and an independent IT expert.

Funding

The modernisation of the HFEA, which began in 2002/03, had considerable financial implications. It was recognised early in the year that the agreed budget would not be sufficient to fund the necessary developments, particularly in Regulation. Following a public consultation, HFEA proposals for a significant increase in the licence fees were agreed by DH. By agreement with the Department, the implementation of the increase was held back until 1st April 2003 to avoid adversely affecting the clinics. DH made £607,000 available to cover the resulting shortfall in fee income for the year. A further £650,000 was allocated by the Department for other developments.

We are building on this, and other work already underway, in the current year.

5. Review of Effectiveness

As Accounting Officer, I have responsibility for reviewing the effectiveness of the system of internal control. My review of the effectiveness of the system of internal control is informed by the work of the internal auditors and the executive managers within the HFEA, who have responsibility for the development and maintenance of the internal control framework, and comments made by the external auditors in their Management Letter and other reports. I have been advised on the implications of the result of my review of the effectiveness of the system of internal control by the Authority, the Audit Committee and the Senior Management Team, and a plan to address weaknesses and ensure continuous improvement of the system is in place.

The new risk strategy includes an organisation-wide process for reviewing risk and monitoring implementation of controls. This takes place at departmental level, the SMT, Standing Committees and the Authority itself.

- The Authority will review the effectiveness of risk management at least twice during the year. A mid-year report will be presented to the Authority in October 2003, and a full report from the Audit Committee at the year end.

- The Audit Committee held an extra meeting in February 2003 to consider the draft risk strategy and register. Risk is now a regular item on the agenda. There will be a formal review in September 2003, and a report will be submitted to the Authority at the year end.

- **SMT:** Directors are closely involved in ensuring risk is identified and managed. The SMT will review this process every 2 months, and will have a full discussion on progress in implementing risk management, with a review of high-level risks, at an away day in September 2003.

- **Risk Management Group (RMG):** This group, which includes all middle managers responsible for key services, is charged with the regular monitoring of implementation of controls over risk and identifying new and changed risks. Group members will also be the focus for developing risk awareness in each part of the organisation. In the period June-August 2003, the RMG will be reviewing the high-level risks and related controls. This will include consideration of whether any new risks have emerged. Alongside there will be a programme of work with each department to review detailed risk registers, and the work being done to address them. The Group is led and supported by the Director of Resources and Corporate Development.

  Other Staff: It is recognised that all staff must be involved in, and have some understanding of, risk management. The individual members of the RMG will be a key focus in developing this awareness. During July-September 2003 workshops will be held with staff in each functional group, to discuss their risk register and the related controls. The aim is to link risk management to the implementation of the Business Plan, to demonstrate that risk is not some esoteric activity, but a central part of what they do.

- **Internal Audit:** The Internal Audit Team has been proactive throughout the year in helping the HFEA identify risk. They have an explicit role in scrutinising the risk management process and reporting on this to the Audit Committee.

The aim during this year is to integrate the management of risk within the wider business planning process, and I am confident that this process will be fully embedded in the organisation by 31st March 2004.

Ms Angela McNab
Interim Chief Executive
10th July 2003

Human Fertilisation and Embryology Authority 2002-2003

Certificate and Report of the Comptroller and Auditor General to the Houses of Parliament

I certify that I have audited the financial statements on pages 46 to 58 under Section 6(4) of the Human Fertilisation and Embryology Act 1990. These financial statements have been prepared under the historical cost convention, as modified by the revaluation of certain fixed assets, and the accounting policies set out on page 48.

Respective responsibilities of the Authority, the Chief Executive and Auditor

As described on page 41, the Authority and Chief Executive are responsible for the preparation of the financial statements in accordance with the Human Fertilisation and Embryology Act 1990 and directions made thereunder by the Secretary of State with the approval of the Treasury, and for ensuring the regularity of financial transactions. The Authority and Chief Executive are also responsible for the preparation of the Foreword. My responsibilities, as independent auditor, are established by statute and guided by the Auditing Practices Board and the auditing profession's ethical guidance.

I report my opinion as to whether the financial statements give a true and fair view and are properly prepared in accordance with the Human Fertilisation and Embryology Act 1990 and the directions made thereunder by the Secretary of State, and whether in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them. I also report if, in my opinion, the Foreword is not consistent with the financial statements, if the Authority has not kept proper accounting records, or if I have not received all the information and explanations I require for my audit.

I review whether the statement on pages 42 to 43 reflects the Authority's compliance with Treasury's guidance 'Corporate Governance: Statement on Internal Control'. I report if it does not meet the requirements specified by Treasury, or if the statement is misleading or inconsistent with other information I am aware of from my audit of the financial statements.

Basis of audit opinion

I conducted my audit in accordance with United Kingdom Auditing Standards issued by the Auditing Practices Board. An audit includes examination, on a test basis, of evidence relevant to the amounts, disclosures and regularity of financial transactions included in the financial statements. It also includes an assessment of the significant estimates and judgements made by the Authority and Chief Executive in the preparation of the financial statements, and of whether the accounting policies are appropriate to the Authority's circumstances, consistently applied and adequately disclosed.

I planned and performed my audit so as to obtain all the information and explanations which I considered necessary in order to provide me with sufficient evidence to give reasonable assurance that the financial statements are free from material misstatement, whether caused by error, or by fraud or other irregularity and that, in all material respects, the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

In forming my opinion I have also evaluated the overall adequacy of the presentation of information in the financial statements.

Opinion

In my opinion:

- the financial statements give a true and fair view of the state of affairs of the Human Fertilisation and Embryology Authority at 31 March 2003 and of the deficit, total recognised gains and losses and cash flows for the year then ended and have been properly prepared in accordance with the Human Fertilisation and Embryology Act 1990 and directions made thereunder by the Secretary of State; and
- in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

My observations on these financial statements are set out in my report on page 45.

John Bourn
Comptroller and Auditor General
Date 15th July 2003

National Audit Office
157-197 Buckingham Palace Road
Victoria
London SW1W 9SP

Human Fertilisation and Embryology Authority 2002-2003

Supplementary statement by the Comptroller and Auditor General in respect of material included at pages 1 to 35 of this Annual Report, not included with the financial statements to which the audit opinion above relates.

In respect alone of my responsibility under United Kingdom auditing standards to read the other information included with financial statements on which I express an audit opinion, I have read the additional information on pages 1 to 35 which was not included with the financial statements on which I reached the audit opinion set out in my Certificate above and considered whether it is consistent with the audited financial statements. I have considered the implications for my audit opinion if I have thereby become aware of any apparent mis-statement or material inconsistencies with the financial statements. I have not considered the effects of any events since the date of my Certificate.

In this regard, my audit opinion on the financial statements is unchanged.

John Bourn
Comptroller and Auditor General
Date 24th October 2003

National Audit Office
157-197 Buckingham Palace Road
Victoria
London SW1W 9SP

Report by the Comptroller and Auditor General

Accounts of the Human Fertilisation and Embryology Authority 2002-2003

Background

1. The Human Fertilisation and Embryology Authority was set up in 1991 under the Human Fertilisation and Embryology Act 1990. The Authority's principal task is to license and monitor clinics carrying out *in vitro* fertilisation, donor insemination and human embryo research. It is also required to maintain a register of licensed treatments performed in the United Kingdom.
2. Under Section 16 of the Act, the Authority is required to charge fees for the issue and renewal of licences. These licence fees consist of an initial fee plus an additional fee based on the number of treatment cycles performed by the clinic.
3. Clinics must notify the Authority of all licensed treatments that they have performed. With this information, the Authority will calculate the appropriate fees and invoice clinics for these treatments. However, in my Reports on the 2000-01 and 2001-02 accounts, I noted that the Authority had identified that not all treatment cycles undertaken by clinics had been reported to it and therefore not all income had been identified and billed for.
4. In normal circumstances, I would have undertaken additional procedures to verify the income due, but in this case I was unable to do so. This is because, under Section 33 of the Act, it is an offence for the Authority to disclose information held on the Register to any third party. The Act limits access to the Authority's own staff and I therefore have no access to the detailed information used to calculate licence fee invoices, nor to the records maintained by individual centres.
5. Because of these legal restrictions on my access to information, there were no other satisfactory audit procedures that I could have adopted to confirm the completeness of the licence fee income which should have been collected.
6. Given these factors, I qualified my audit opinion on the 2000-01 and 2001-02 accounts because the possible effect of the limitation of the scope of my audit was material.

Actions taken by the Authority in 2002-2003

7. Following my reports on the Authority's 2000-01 and 2001-02 accounts, the Authority recognised that the system for calculating fees and invoicing clinics was unsatisfactory and implemented a number of changes in its business processes to attempt to improve this position and provide reliable estimates of the likely income due to it:
   - From April 2002, the Authority required clinics to provide them with the number of treatments undertaken on a monthly, rather than annual, basis. The Authority would then invoice the clinics for fees due monthly. Invoices are now issued on a more timely basis and clinics can reconcile the invoices they receive to the number of treatments they have reported.
   - As a result of changing their billing procedures, the licence fee income shown in the Authority's 2002-03 accounts is higher than would be normal, £2.52 million against £1.57 million in 2001-02. This is a transitional year for the Authority, with the fee income figure in the accounts recording both the final treatments invoiced under the old annual billing system (accounting for some £0.87 million) and those invoiced under the new monthly billing system (some £1.65 million).
   - From October 2002, the Authority began a comprehensive programme of clinic audits which included reviewing a sample of ten per cent of treatments at all clinics performing chargeable treatments. These audits assessed whether the treatments had been reported to the Authority within agreed timescales and whether the Authority had then invoiced the clinics for the fees due. The clinic audits concluded that in all material respects all treatments that had occurred had been properly reported to the Authority and were invoiced.
   - The Authority reviewed treatment cycles reported to it that were undertaken between August 1991 and December 2002 at a sample of eleven clinics to establish the extent of any likely under billing. The review concluded that all outstanding chargeable treatments reported to the Authority had now been billed.

     The Authority has also estimated that 1.6% of treatment cycles, since 1991, have never been reported to it in the first place and have therefore never been billed. This equates to a maximum potential loss of income of some £189,000 since 1991. The Authority is currently assessing these results to help decide whether any of this income can be recovered. Future clinic inspections will focus on the weakest areas and clinics, bearing in mind cost benefit considerations.

Basis of unqualified audit opinion

8. My staff have worked closely with the Authority in agreeing the actions required. As a result of this, and following our review of the actions taken and their results, I am content that I now have sufficient evidence to demonstrate that, in all material respects, treatments that have taken place have been reported to the Authority, were billed and the licence fee income figures are therefore materially correct.
9. Given this, the reasons why I qualified my audit opinions on the 2000-01 and 2001-02 financial statements no longer apply and I therefore have not qualified my opinion on the Authority's 2002-03 financial statements in this regard.

Further action being taken by the Authority

10. The Authority has taken a number of actions designed to ensure robust, verifiable and collectable fee income from clinics:
    - From 1 April 2003, the Authority implemented a new fee structure with increased rates for in-vitro fertilisation and donor insemination treatment cycles, with the intention of funding a stronger regulatory and inspection regime.
    - The Authority's clinic audit process will continue into 2003-04, but this will be integrated more into the wider clinic inspection process.
    - The Authority has developed its information systems further. It established a new more robust data register and, during 2003-04, information from the old registers will be validated and transferred onto the new system. The Authority intends to introduce electronic data interchange with clinics to replace current manual processes and give faster more accurate procedures. Investigation has commenced into the practicalities of this. Developments are overseen by an Information Management Programme Board, chaired by the Chief Executive, and involving Authority members and an independent IT expert.
    - As a result of this improved information, the Authority plans to refine its income recognition policy from 2003-04 to account for income when the treatment cycle takes place, rather than when it is reported to the Authority.

John Bourn
Comptroller and Auditor General
Date 15th July 2003

National Audit Office
157-197 Buckingham Palace Road
Victoria
London SW1W 9SP

Income and Expenditure Account for the Year Ended 31 March 2003

	Notes	2002/2003 £	2001/2002 £
Income			
Gross Income	2	5,532,532	2,810,949
Transfer from Government Grant Reserve (Capital Spend)	11	79,390	72,550
		5,611,922	2,883,499
Expenditure			
– Staff Costs	3	2,523,912	1,363,038
– Other Operating Charges	4	3,028,529	1,285,338
– Depreciation	5	77,472	68,315
– (Surplus)/Loss on Disposal of Fixed Assets		(353)	154
Total Expenditure		5,629,560	2,716,845
Operating (Deficit)/Surplus		(17,638)	166,654
Exceptional Item: Increase In Pension Provision	9	(288,330)	(26,713)
– Notional Interest (Capital Charges)	1(g)	23,987	22,363
(Deficit)/Surplus on Ordinary Activities		(281,981)	162,304
– Write back of Notional Interest	1(g)	(23,987)	(22,363)
(Deficit)/Surplus for the Financial Year		(305,968)	139,941
Retained (Deficit) brought forward	11	(434,451)	(572,991)
Adjustment to 2000-2001 Government Grant Reserve		-	(1,401)
Retained (Deficit) carried forward	11	(740,419)	(434,451)

All operations are continuing.

Statement of Total Recognised Gains and Losses for the Year Ended 31 March 2003

	Notes	2002/2003 £	2001/2002 £
(Deficit)/Surplus for the Financial Year		(305,968)	139,941
Unrealised Surplus on Revaluation of Fixed Assets		-	150
Total Recognised (Losses)/Gains for the Year		(305,968)	140,091
Prior Period Adjustment		-	(640,800)
Total (Losses) Recognised Since Last Annual Report		(305,968)	(500,709)

The notes on pages 48 to 58 form part of these Accounts.

Balance Sheet as at 31 March 2003

	Notes	31 March 2003 £	31 March 2002 £
Fixed Assets	5	199,158	174,242
Current Assets:			
– Debtors: Amounts Falling Due Within One Year	6	650,225	543,601
– Cash at Bank and in Hand	17	29,191	35,033
Creditors: Amounts Falling Due Within One Year	7	(199,820)	(343,654)
Net Current Assets		479,596	234,980
Long Term Liabilities			
Provisions for Liabilities and Charges	9	(1,220,015)	(667,513)
Total Assets less Current Liabilities		(541,261)	(258,291)
Financed By			
Capital and Reserves			
– Government Grant Reserve (Capital Spend)	11	186,641	163,643
– Income and Expenditure Reserve	11	(740,419)	(434,451)
– Revaluation Reserve	11	12,517	12,517
		(541,261)	(258,291)

The notes on pages 48 to 58 form part of these Accounts.

Ms Angela McNab
Interim Chief Executive
10 July 2003

Cash Flow Statement for the Year Ended 31 March 2003

	Notes	2002/2003	2001/2002
Operating Activities			
Net Cash (Outflow)/Inflow	18(a)	(6,195)	18,938
Capital (Expenditure)/Income			
– Purchase of Fixed Assets	5	(102,388)	(162,701)
– Cash Received on Disposal of Assets		353	-
Net Cash (Outflow) Before Financing		(108,230)	(143,763)
Financing			
– Receipts of Government Grants for Purchase of Fixed Assets	11	102,388	162,701
– Net Cash Inflow from Financing		102,388	162,701
(Decrease)/Increase in Cash	18(b)	(5,842)	18,938

The notes on pages 48 to 58 form part of these Accounts.

Notes to the Accounts

1 Accounting policies

(a) Accounting Convention

The HFEA's accounts are prepared in accordance with the provisions of the Human Fertilisation and Embryology Act 1990 and an Accounts Determination issued by the Secretary of State for Health in May 1997 (reproduced as an appendix to these accounts).

These accounts are prepared, in accordance with applicable accounting standards, under the historical cost convention modified to allow for the revaluation of fixed assets. Without limiting the information given, the accounts meet the accounting and disclosure requirements of the Companies Acts and Accounting Standards issued or adopted by the Accounting Standards Board so far as those requirements are appropriate.

(b) Fixed Assets

Fixed Assets include tangible fixed assets and the costs of acquiring or creating computer systems or software. Only items, or groups of related items, costing £1,000 or more and with individual values over £250, are capitalised. Those costing less are treated as revenue expenditure.

Assets purchased prior to the current financial year are indexed annually using the Office for National Statistics' indices if there is a material difference between historic cost and current replacement cost. In 2002/03, HFEA decided that no material adjustment was necessary and therefore modified historic cost accounting has not been applied in financial year 2002/03.

Gains and losses arising on indexation are normally taken to the government grant reserve. However, deferred government grant is released to match downward indexation of particular assets when there are no related existing credits within the government grant reserve.

(c) Depreciation

Depreciation is provided on all tangible fixed assets at rates calculated to write off the cost of each asset evenly over its expected useful life. Expected useful lives are as follows:

Computer equipment and software	**3 years**
Office equipment	**4 years**
Furniture, fixtures and fittings	**4 years**

Installations and improvements to leasehold property have been fully depreciated.

(d) Operating Leases

Operating leases are charged to the accounts on a straight line basis over the lease term.

(e) Register of Information

Expenditure on development of the computer programme for the Register of Information is charged to the Income and Expenditure Account as it is incurred.

(f) Government Grants

Government grants received for revenue expenditure are credited to income in the year to which they relate. Government grants received for capital expenditure are credited to the government grant reserve and released to the Income and Expenditure Account to match depreciation and downward indexation, where appropriate.

(g) Notional Charges

In accordance with Treasury guidance, notional interest at 6% of the average capital employed has been credited in the Income and Expenditure Account amounting to £23,987 (2001/2002 - £22,363).

With effect from financial year 2003/04, this notional interest charge will be calculated at 3.5%.

(h) Pensions

Past and present employees are covered by the provisions of the Principal Civil Service Pension Scheme. The defined benefit elements of the schemes are unfunded and are non-contributory except in respect of dependents' benefits. The HFEA recognises the expected cost of these elements on a systematic and rational basis over the period during which it benefits from employees' services by payment to the Principal Civil Service Pension Scheme (PCSPS) of amounts calculated on an accruing basis. Liability for payment of future benefits is a charge on the PCSPS. In respect of the defined contribution elements of the schemes, the HFEA recognises the contributions payable for the year.

(i) Fees and Charges Guide

From 2002/03 it was agreed with the Department of Health that the HFEA is a single purpose organisation. These accounts therefore no longer show a note of segmental information for different services or forms of services, as required by HM Treasury's "The Fees and Charges Guide".

2. Gross Income

Gross income is made up of Government grants received in the year and of licence fee and other incomes which are recorded on an accruals basis.

Analysis of Income	2002/2003 £	2001/2002 £
Licence Fee Income		
– Annual billing	874,094	1,574,816
– Monthly billing	1,650,434	-
Other Income	2,392	2,181
Widowers Contributions Receipts		(10,647)
Cash Received from the Department of Health	3,108,000	
Less Capital Grant element	(102,388)	(162,701)
	3,005,612	1,407,300
	5,532,532	2,810,949

Income received from the Department of Health included contributions from the devolved administrations for Scotland, Wales and Northern Ireland.

As from 1st April 2002, the process for billing centres for Licence fees was changed. Previously, centres were invoiced once per year close to the anniversary of licence renewal date, to cover all billable treatment cycles reported in the preceding 12 months. From April 2002, treatment cycles have been reported each month and invoiced in the following month. The point at which a cycle becomes billable is assumed to be when it is reported under these monthly invoicing procedures.

An accrual has been made to include income from cycles reported in March 2003, which were invoiced after the year end. Cycles reported up to March 2002 and not previously invoiced continued during 2002/03 to be invoiced at the licence renewal anniversary date. The effect of the change in process is to bring forward the timing of payments by centres with a consequential one-off rise in income to HFEA in 2002/03. However, over a multi-year period neither income to HFEA, nor payments by centres is raised by this change in invoicing process.

HFEA is currently developing its systems to enable earlier reporting of treatment cycles and hence enable income to be recognised at the time of treatment as opposed to the subsequent point in time when they are reported under the Authority's current invoicing procedures. It is planned that the Accounts for financial year 2003/04 will reflect this new accounting treatment.

At the time of producing the 2001/2002 annual Accounts, HFEA management were in receipt of a draft report by internal auditors drawing attention to discrepancies between the total number of cycles reported to HFEA and the number billed. At the time an assumption was made that this was due to failure to bill all reported cycles. Subsequently these discrepancies were investigated further, and the main cause of the discrepancies was found to be the fact that not all cycles are billable. Some do not attract a licence fee charge under HFEA rules. There were also significant invoicing timing differences contributing to the apparent discrepancies. As a result of these further investigations, HFEA no longer believes there is any significant failure to invoice all reported cycles that are billable.

4. Staff Costs

	2002/2003 £	2001/2002 £
All Staff		
Salaries – HFEA Staff	1,381,525	771,081
Salaries – Seconded Staff	138,174	86,064
Social Security Costs	128,721	64,703
Superannuation Costs – Seconded Staff	24,770	13,180
Superannuation Costs – HFEA Staff	131,413	103,055
Agency/Temporary Staff	561,119	220,011
Compensation Payment	31,600	-
	2,397,322	1,258,094
Members Costs	126,590	104,944
Total	2,523,912	1,363,038

The average monthly number of full time and part-time staff employed, including secondees and temporary staff, during the year was as follows:

	2002/2003	2001/2002
Management	3	4
Administrative	54	36
	57	40

Remuneration of Key Management

	2002/2003 £	2001/2002 £
Chief Executive		
Dr. Maureen Dalziel		
(1 April 2002 - 17 November 2002)		
Total Paid to Seconding Body	47,715	85,067
Interim Chief Executive		
Ms Angela McNab		
(11 November 2002 - 31 March 2003)		
Total Paid to Seconding Body	45,808	-

Pensions Entitlements

The Chief Executive from 1 April to 17 November 2002, Dr Maureen Dalziel, was on secondment from the London School of Hygiene and Tropical Medicine. The interim Chief Executive from 11 November 2002 onwards, Ms Angela McNab, was on secondment from the Department of Health. HFEA was therefore not responsible for the pension arrangements of either individual.

Other Senior Managers

The Resource Accounting Manual requires the HFEA to provide information on the age, salary and pension rights of the named individuals who are the "most senior managers" of the HFEA, subject to the individuals concerned consenting to disclosure. James Stockwell and Ann Furedi have declined to give their consent to the publication of their personal details and their information is not therefore included in the note.

The Salary and pension entitlements of the remaining Senior Manager in HFEA during the year was as follows:

	Age	Salary	Real Increase in Pension at 60	Total Accrued Pension at 60
Barry MacDonald	55	£5,001 - £10,000	£0 - £2,500	£0 - £5,000
(joined HFEA 1st March 2003)				

Remuneration of Authority Members

Chairman - Suzi Leather	2002/2003	2001/2002
	£	£
Remuneration - in the bands of:	£20,000 - £25,000	£0 - £5,000

Pension contributions in the band of £0 - £2,500 were made on behalf of Suzi Leather in 2002/03 (2001/02 - nil). The real increase in pension at age 60 during the year was in the band £0 - £2,500. The total accrued pension at 60 as at 31 March 2003 was in the band £0 - £5,000. At the balance sheet date, Suzi Leather was aged 46.

Remuneration in the band of £10,000 - £15,000 was paid to the previous Chairman, Mrs Ruth Deech, during financial year 2001/02. No pension contributions were paid.

Members Costs (including Chairman)	2002/2003	2001/2002
	£	£
Total fees payable to members	115,893	95,775
Social Security Costs	8,334	9,169
Superannuation Costs	2,363	-
	126,590	104,944

The Deputy Chairman received a fee of £180 per day. Members received a fee of £165 per day. No pension contributions were paid on behalf of any Board Member other than the Chairman. Remuneration payable to individual members for attendance at meetings and inspections during the financial year was in the following bands:-

Lady Julia Tugendhat (Deputy Chair - retired 6/11/02)
Professor Thomas Baldwin (Deputy Chair with effect from 7/11/02)
Dr Sue Avery (retired 6/11/02)
Professor David Barlow
Ms Claire Brown (appointed 2/12/02)
Professor Iain Cameron
Professor Christine Gosdon (retired 6/11/02)
Professor Andrew Grubb
Professor Neva Haites (appointed 2/12/02)
Dr Maybeth Jamieson (appointed 2/12/02)
Mr Simon Jenkins
Professor Henry Leese (resigned 23/9/02)
Professor Stuart Lewis (retired 6/11/02)
Mr Walter Merricks (appointed 02/12/02)
Rt. Revd. Dr Michael Nazir-Ali
Ms Sharmila Nebhrajani
Dr Francoise Shenfield (retired 6/11/02)
Mrs Jean Smith (retired 6/11/02)
Mrs Liz Woods (retired 6/11/02)

Mrs Jane Denton (Director of Sub-Committees)
Professor Christopher Barratt
Professor Peter Braude
Mr Ivor Brecker
Ms Sara Nathan

4 Other Operating Charges

	2002/2003 £	2001/2002 £
Operating lease payments		
– Land and Buildings	246,880	110,450
– Other Leases	10,533	12,194
Accommodation	172,628	91,287
Travel & Subsistence	211,095	110,198
Attendance Fees – Inspectors	26,192	20,959
Professional & Administrative Fees	1,005,435	430,059
Audit Fees		
– External	32,500	15,000
– Internal	21,620	16,723
Register of Information	305,596	219,305
Stationery, Photocopying & Printing	178,023	45,877
Telephones & Postage	68,352	41,804
Training & Development	122,842	27,359
Recruitment & Advertising	345,220	51,482
Conferences & Meeting Expenses	39,305	14,588
Library & Reading Materials	29,774	9,608
Sundry Office Equipment	83,120	13,832
IT Costs (Including Website)	95,806	36,515
Miscellaneous	33,608	13,863
Permanent Diminution in Value of Fixed Assets	-	4,235
Total	3,028,529	1,285,338

5. Fixed Assets as at 31 March 2003

	Computer Equipment £	Office Equipment £	Furniture & Fittings £	Installations £	Totals £
Cost/valuation as at 31 March 2002	152,246	71,517	100,420	116,936	441,119
Additions	84,631	17,757	-	-	102,388
Disposals	(11,909)	-	(12,040)	-	(23,949)
Revaluation	-	-	-	-	-
Transfers	-	116,936	-	(116,936)	-
As at 31 March 2003	**224,968**	**206,210**	**88,380**	**-**	**519,558**
Depreciation as at 31 March 2002	43,073	41,387	95,217	87,200	266,877
Charge for the year	53,928	21,619	1,925	-	77,472
Disposals	(11,909)	-	(12,040)	-	(23,949)
Revaluation	-	-	-	-	-
Transfers	-	87,200	-	(87,200)	-
As at 31 March 2003	**85,092**	**150,206**	**85,102**	**-**	**320,400**
Net Book Value (NBV)					
At 31 March 2003	**139,876**	**56,004**	**3,278**	**-**	**199,158**
At 31 March 2002	109,173	30,130	5,203	29,736	174,242
Increase/(Decrease) in NBV	**30,703**	**25,874**	**(1,925)**	**(29,736)**	**24,916**

As recorded in note 1(b) to these Accounts, modified historic cost accounting has not been applied to fixed assets this year, as there is no material difference between historic cost and current replacement cost.

6. Debtors: Amounts Falling Due Within One Year

	31 March 2003	31 March 2002
Licence Fee & Accrued Income	462,962	394,084
Other Debtors	16,425	9,717
Pre-payments	170,838	139,800
	650,225	543,601

7. Creditors: Amounts Falling Due Within One Year

	31 March 2003	31 March 2002
Trade Creditors	2,240	2,349
Other Taxes and Social Security	4,486	4,450
Accruals and Deferred Income	193,094	336,855
	199,820	343,654

ension Arrangements (HFEA Staff)

As per 2001 Statutory Instrument No. 1587, HFEA staff were conditionally admitted to the Principal Civil Service Pension Scheme as from 1st April 2000, transferring from the HFEA by-analogy Scheme.

The PCSPS is an unfunded multi-employer defined benefit scheme, however the HFEA is unable to identify its share of the underlying assets and liabilities. A full actuarial valuation was carried out as at 31 March 1999. Details can be found in the resource accounts of the Cabinet Office: Civil Superannuation **(www.civilservice-pensions.gov.uk).**

For 2002-03, employer's contributions of £133,776 were payable to the PCSPS (2001/2002 £103,055) at rates in the ranges of 12 to 18.5 per cent of pensionable pay, based on salary bands. Rates will remain the same for the next year, subject to revalorisation of the salary bands. Employer contributions are to be reviewed every four years following a full scheme valuation by the Government Actuary. The contribution rates reflect benefits as they are accrued, not when the costs are actually incurred, and reflect past experience of the scheme.

Employees joining after 1 October 2002 could opt to open a partnership pension account, a stakeholder pension with an employer contribution. No member of staff exercised this option during financial year 2002/03

sions For Liabilities and Charges

	2002/2003 £	2001/2002 £
Accrued Pension Liability Brought Forward	667,513	640,800
Movement in Liability for Pensions Transfer During the Year:		
Opening Creditor	216,638	-
Payments to/from JSS	(15,354)	-
Current Year Notional Pension Costs	62,888	-
Increase in Provision for Year	288,330	26,713
Total Provision for Liabilities and Charges	1,220,015	667,513

Further information about the HFEA's transfer from its by-analogy pension scheme into membership of the PCSPS is provided in the Foreword to these Accounts, under "Financial Results for 2002/03 and Going Concern".

ost Balance Sheet Events

In June 2003, the funding required to complete the transfer of the HFEA into membership of the PCSPS, in the sum of £1.22m, was received. Payment was made in the same month to the Civil Superannuation Vote. This is however a non-adjusting post balance sheet event.

11. Government Grant Reserve (Capital Spend), Capital and Reserves

	Government Grant Reserve (Capital Spend) £	Income and Expenditure Reserve £	Revaluation Reserve
Balance at 31 March 2002	163,643	(434,451)	12,517
2002/03 Capital Grant	102,388	-	-
Transfer to Income & Expenditure Account for Depreciation	(77,472)	-	-
Transfer to Income & Expenditure Account, Adjustment to Opening Position	(1,918)	-	-
Deficit for the Year	-	(305,968)	-
Balance at 31 March 2003	186,641	(740,419)	12,517

12. Financial Commitments

The HFEA is committed to make the following operating lease payments during the next financial year:

	2002/2003	2001/2002
Land and Buildings		
Leases which expire within 1 year	26,000	110,450
Leases which expire within 2 to 5 years	238,590	-
Other Leases		
Leases which expire within 1 year	2,617	6,102
Leases which expire within 2 to 5 years	7,264	-

13. Capital Commitments

At the balance sheet date the HFEA had no capital commitments.

14. Contingent Liabilities

HFEA is in discussions with an individual regarding termination of a secondment agreement. No disclosure is made of a contingent liability as this may prejudice the outcome of an industrial tribunal.

15. Related Party Transactions

The Department of Health is regarded as a related party. During the year the HFEA has had various material transactions with the Department and with some NHS Trusts for which the Department of Health is regarded as the parent Department.

a) The following members of the HFEA board have senior management responsibilities at either NHS Trusts or private clinics that are regulated by the HFEA.

Dr. Sue Avery, Scientific Director, Bourn Hall. Fees charged by HFEA to Bourn Hall during the year amounted to £57,158. The amount outstanding at 31st March 2003 was £17,000.

Professor David Barlow, Head of Oxford Fertility Unit and HFEA Person Responsible. Fees charged by HFEA to the Oxford Fertility Unit amounted to £59,842 during the year. The amount outstanding at 31 March 2003 was £5,780.

Professor Christopher Barratt, Scientific Director, Birmingham Women's Hospital. Fees charged by HFEA to the Birmingham Women's Hospital amounted to £59,368 during the year. The amount outstanding at 31st March 2003 was £1,360.

Professor Peter Braude, Guy's, Kings and St Thomas' School of Medicine, Head of the Department of Women's Health, Director of the Centre for Pre-Implantation Genetic Diagnosis Guy's & St Thomas's Trust, Honorary Consultant in Gynaecology Guy's & St Thomas's Trust. Fees charged by HFEA to the Guy's and St Thomas's Hospital NHS Trust amounted to £37,248. The amount outstanding at 31st March 2003 was £8,634.

Professor Neva Haites, Professor in Medical Genetics, University of Aberdeen. Fees charged by HFEA to the University of Aberdeen during the year amounted to £34,536. The amount outstanding at 31st March 2003 was £9,494.

Dr. Maybeth Jamieson, Consultant Embryologist Glasgow Royal Infirmary. Fees charged by the HFEA to Glasgow Royal Infirmary during the year amounted to £66,822. The amount outstanding at 31st March 2003 was £26,900.

Dr Francoise Shenfield, Clinical Lecturer in Infertility, Reproductive Medicine Unit, University College Hospital; full time consultant at London Women's Clinic, Harley Street. Fees charged by HFEA to University College Hospital during the year amounted to £3,962. The amount outstanding at 31st March 2003 was £1,174. Fees charged to the London Women's Clinic amounted to £24,544. The amount outstanding at 31st March 2003 was £12,452.

b) **Clare Brown,** Executive Director of CHILD, the National Infertility Support Network. A payment of £15,000 was made to CHILD by HFEA during the year for survey and research

c) In the Annual Report all Members' interests are disclosed and Members are expected to declare any conflict of interest in discussions held by the Authority. There is currently no system in place to record conflict of interests involving staff of the HFEA, however one is to be developed in the coming year.

rformance against key financial targets

The HFEA has one key financial target in that it must ensure that it remains within the cash limit set by the Department of Health. During 2002/03 HFEA managed income and expenditure so that draw downs were kept to within the Department's cash allocation. A total of £3,108,000 was drawn down from the Department during 2002/03, out of a total available cash allocation of £3,846,000.

17. Cash at Bank and in Hand

	2002/2003	2001/2002
Cash at Bank and in Hand	25,329	30,994
OPG Account	3,862	4,039
	29,191	35,033

18. Notes to the Cash Flow Statement

	2002/2003	2001/2002
a. Reconciliation of Operating Surplus to Net Cash (Outflow)/Inflow From Operating Activities:		
Operating (Deficit)/Surplus	(305,968)	139,941
(Profit)/Loss on Disposals of Fixed Assets	(353)	154
Miscellaneous	-	364
Depreciation Charges	77,472	68,315
Downward Indexation Charge	-	4,235
(Increase) in Debtors	(106,624)	(302,140)
(Decrease)/Increase in Creditors	(143,834)	153,906
Transfer from Government Grant (Capital Spend)	(79,390)	(72,550)
Increase in Provision for Pension Transfer Costs:	552,502	26,713
Net Cash (Outflow)/Inflow from Operating Activities	(6,195)	18,938

b. Analysis of Changes in Cash

	At 31 March 2002		
Cash at Bank and in Hand	35,033	(5,842)	29,191

16 Financial Instruments

FRS 13, Derivatives and Other Financial Instruments, requires disclosure of the role financial instruments have had during the period in creating or changing the risks an entity faces in undertaking its activities.

As permitted by FRS 13, debtors and creditors which mature or become payable within 12 months from the balance sheet date have been omitted from this note.

Liquidity Risk

The principal source of revenues (46% of total gross income) is derived directly from the number of IVF and DI treatment cycles performed by the licensed clinics and reported to the HFEA. The remaining source of revenue is derived from Government grants made on a cash basis.

There are procedures in place to identify late and non-reporting of treatment cycles by clinics and also procedures for chasing up debts. HFEA is therefore not exposed to significant liquidity risks.

Investments and Interest Rate Risk

The HFEA follows an investment policy of placing any surplus funds on deposit in an interest bearing bank account. Interest income was less than £1,000 of the revenues of the HFEA, and the HFEA is not therefore exposed to significant interest rate risk.

Financial Assets	Total	Non-Interest bearing cash deposits	Floating-rate cash deposits
	£	£	£
At 31 March 2003	**28,791**	**-**	**28,791**
At 31 March 2002	34,819	20,319	14,500

Petty cash held on site amounted to £400 (2001/02: £214).

The fair value of the financial assets was equal to the book value.

Financial Liabilities

The HFEA had no financial liabilities at 31 March 2003 requiring disclosure under FRS 13.

Foreign Currency Risk

There were minimal foreign currency transactions conducted by the HFEA during the year ended 31 March 2003. There was therefore no significant foreign currency risk during the year.

Appendix

The Human Fertilisation and Embryology Authority

Accounts Determination

The Secretary of State, with the approval of the Treasury, in pursuance of Section 6 of the Human Fertilisation and Embryology Act 1990, hereby gives the following determination:

Direction given by the Secretary of State

1. In this determination "the Authority" means the Human Fertilisation and Embryology Authority.

Form of Accounts

2. The Authority shall prepare accounts for the financial year ended 31st March 1997 and subsequent financial years comprising:
   a) a Foreword;
   b) an Income and Expenditure account;
   c) a Balance Sheet;
   d) a Cash Flow Statement; and
   e) a Statement of Total Recognised Gains and Losses;
   including such notes as may be necessary for the purposes referred to in the following paragraphs.

3. The Accounts shall give a true and fair view of the income and expenditure and cash flows for the financial year, and the state of affairs as at the end of the financial year.

4. Subject to this requirement, the Accounts shall be prepared in accordance with:
   a) Generally accepted accounting practice in the United Kingdom (UK GAAP);
   b) The disclosure and accounting requirements contained in "The Fees and Charges Guide" (in particular those relating to the need for appropriate segmental information for services or forms of service provided) and in other guidance which the Treasury or the Secretary of State may issue from time to time in respect of Accounts which are required to give a true and fair view;
   c) The accounting and disclosure requirements given in "Government Accounting" and in "Executive NDPBs: Annual Reports and Accounts Guidance"; as amended or augmented from time to time: insofar as these are appropriate to the Authority and are in force for the financial year for which the Statement of Accounts is to be prepared.

5. Clarification of the application of the accounting and disclosure requirements of the Companies Act and accounting standards is given in Schedule 1 attached. Additional disclosure requirements are set out in Schedule 2 attached.

6. The Income and Expenditure Account and Balance Sheet shall be prepared under the historical cost convention modified by the inclusion of:
   a) fixed assets at their value to the business by reference to current costs; and
   b) stocks valued at the lower of net current replacement cost (or historical cost if this is not materially different) and net realisable value.

7. This Accounts Determination supersedes that dated 26th April 1996 and shall be reproduced as an appendix to the accounts.

Date: 6th May 1997
Signed by the authority of the Secretary of State for Health

P. Kendall
Branch Head (RMF-EAC Division)
Department of Health

Schedule 1

Application of the Accounting and Disclosure Requirements of the Companies Act and Accounting Standards.

Companies Act

1. The disclosure exemptions permitted by the Companies Act shall not apply to the Authority unless specifically authorised by the Secretary of State with the approval of the Treasury.

2. The Companies Act requires certain information to be disclosed in the Directors' Report. To the extent that it is appropriate, the information relating to the Authority shall be contained in the Foreword.

3. When preparing its Income and Expenditure Account, the Authority shall have regard to the profit and loss format 2 prescribed in Schedule 4 to the Companies Act 1985 (as amended).

4. When preparing its Balance Sheet, the Authority shall have regard to the Balance Sheet format 1 prescribed in Schedule 4 to the Companies Act 1985 (as amended). The Balance Sheet totals shall be struck at 'Total Assets less Current Liabilities'.

5. The Authority is not required to provide the additional information required by paragraph 33(3) of Schedule 4 to the Companies Act 1985.

6. The Foreword and Balance Sheet shall be signed by the Chief Executive to the Authority and dated.

Accounting Standards

7. The Authority is not required to include a note showing historical cost profits and losses as described in FRS3.

8. The Authority shall not adopt the Financial Reporting Standard for Smaller Entities unless specifically approved by the Treasury.

Schedule 2

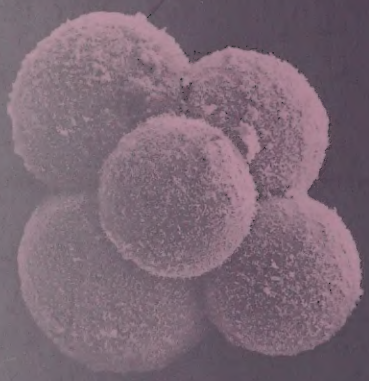
Additional Disclosure Requirements

1. The Foreword shall, inter alia:

   a) State that the Accounts have been prepared in a form determined by the Secretary of State with the approval of the Treasury in accordance with Section 6 of the Human Fertilisation and Embryology Act 1990;
   b) Include a brief history of the Authority and its statutory background.

2. The notes to the accounts shall, inter alia:
   a) Include details for the accounting policies adopted;
   b) Provide further explanations of figures in the accounts where it is considered appropriate for a proper understanding of the accounts;
   c) Include details of the key corporate financial targets set by Ministers together with the performance achieved.

writing and editing Denise Darrell-Lambert design area one photography Charlie Bibby print Raging Thunder



Human Fertilisation and Embryology Authority
Paxton House, 30 Artillery Lane, London E1 7LS, United Kingdom
Telephone: 020 7377 5077
Website: www.hfea.gov.uk
Email: admin@hfea.gov.uk